

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

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| THE CITY OF HUNTINGTON, | : | Civil Action |
| | : | |
| Plaintiff, | : | No. 3:17-cv-01362 |
| | : | |
| v. | : | |
| | : | |
| AMERISOURCEBERGEN DRUG | : | |
| CORPORATION, et al., | : | |
| | : | |
| Defendants. | : | |

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| CABELL COUNTY COMMISSION, | : | Civil Action |
| | : | |
| Plaintiff, | : | No. 3:17-cv-01665 |
| | : | |
| v. | : | |
| | : | |
| AMERISOURCEBERGEN DRUG | : | |
| CORPORATION, et al., | : | |
| | : | |
| Defendants. | : | |

BENCH TRIAL - VOLUME 26
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 14, 2021

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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on June 14, 2021, at 9:00
5 a.m., as follows:

6 THE COURT: Do you have something?

7 MS. WICHT: Good morning, Your Honor. Just a very
8 brief issue. It doesn't relate to Dr. Keyes, the witness
9 who's on the stand. It relates to Ms. Keller who's the next
10 witness up.

11 Your Honor, last night we received -- pursuant to the
12 parties' agreement, we received the documents for Ms. Keller
13 and we received the demonstratives as well.

14 We have raised an issue with the plaintiffs that the
15 demonstratives for Ms. Keller contain opinions and analysis
16 that is not in her report.

17 As to certain -- we're in the process of on-going
18 discussions with the plaintiffs. And as to certain of them,
19 we have resolved the issue. But there are other
20 demonstratives that contain information that is not in
21 Ms. Keller's report.

22 So, for example, she has a -- what Ms. Keller does,
23 very briefly, is just look at prescribers within Cabell
24 County. And she has a slide in her demonstratives, for
25 example, where she compares that information to Queens, New

1 York, Honolulu, Hawaii, Hartford, Connecticut, nationwide.
2 None of that analysis was in her report, Your Honor.

3 And there's one other -- that's slide 3. There's one
4 other slide, slide 8, that has similar -- raises similar
5 issues.

6 Our position is these are new analyses, new opinions.
7 They weren't disclosed in her report. They were first
8 disclosed at 11:00 p.m. last night and she shouldn't be
9 allowed to present them today.

10 THE COURT: Do you want to respond, Mr. Ackerman?

11 MR. ACKERMAN: Yes. I've got a couple of
12 responses, Your Honor.

13 The first one is that we assumed this would come up
14 prior to Ms. Keller taking the stand. So Ms. Singer who is
15 handling that testimony isn't here. But, regardless, we
16 think the slides are wholly consistent with her report and I
17 expect that Ms. Singer will be prepared to address that once
18 she gets to court in order to take Ms. Keller's testimony.

19 MS. WICHT: And that's fine, Your Honor. I've
20 been communicating with Ms. Singer this morning. I didn't
21 realize that she wouldn't be in court right at this
22 particular moment. That's fine.

23 I, I just would say that, then, I don't want to hear
24 any complaints of sandbagging and now the witness is coming
25 to the stand and you're trying to change what we're allowed

1 to do with her because we certainly raised it, you know,
2 this morning and, and -- before court and in court this
3 morning.

4 THE COURT: Well, I'm going to put this off until
5 Ms. Singer is here. I received some good advice from one of
6 my mentors years ago when I started practicing law. He said
7 don't deal with all your problems today. You would be
8 surprised how many of them just go away.

9 MS. WICHT: Good advice, Your Honor. Thank you.

10 THE COURT: All right. Do we have a witness?

11 Is Mr. Hester ready to cross examine?

12 MR. HESTER: Yes, Your Honor. Thank you.

13 THE COURT: Good morning, Dr. Keyes.

14 THE WITNESS: Good morning.

15 THE COURT: You can resume the witness stand and,
16 of course, you're still under oath.

17 **KATHERINE KEYES, PLAINTIFFS' WITNESS, RESUMED THE**
18 **WITNESS STAND**

19 CROSS EXAMINATION

20 BY MR. HESTER:

21 **Q.** Good morning, Dr. Keyes.

22 **A.** Good morning.

23 **Q.** Dr. Keyes, you testified last week that there's a
24 causal connection between exposure to opioids and
25 opioid-related harm; correct?

1 **A.** Yes.

2 **Q.** And you testified that in your view, exposure is
3 synonymous with supply; is that right?

4 **A.** I, I think there's multiple levels of exposure. And
5 one level of exposure can be the supply of prescription
6 opioids to a particular area. But individuals also are
7 exposed to opioids when they personally are using them.

8 **Q.** And you remember Mr. Farrell asked you the question
9 where he said, "Let's try to find another word that helps me
10 understand. Is supply another word for exposure?" And you
11 said, "Yes."

12 Do you remember that?

13 **A.** Yes. In that particular context, I think it was
14 synonymous. But as a general matter, I wouldn't use those
15 two words synonymously in all cases.

16 **Q.** So to be clear, when you talk about exposure or supply,
17 you're talking about opioids that are out in the community
18 and are being used or abused by individuals; correct?

19 **A.** I'm sorry. Can you repeat the question?

20 **Q.** Yes. So when you talk about exposure and supply,
21 you're talking about opioids that are out in the community
22 and are being used or abused by individuals; correct?
23 That's the, that's the supply and the exposure you're
24 focusing on; correct?

25 **A.** Yes.

1 **Q.** And with respect to prescription opioids in particular,
2 that means the pills have either been dispensed by a
3 pharmacy pursuant to a prescription or illegally trafficked
4 or manufactured by criminals. It's one or the other.
5 Correct?

6 **A.** The opioids that are in communities either arrived
7 there through an illegal route or a legal route. So those
8 would be the universe of ways that opioids could get into a
9 community.

10 **Q.** And the source for the legal route, just to set the
11 table -- I think we're on the same page. But to set the
12 table, the source for the legal route would be dispensed by
13 a pharmacy pursuant to a prescription written by a doctor;
14 correct?

15 **A.** I would say in the majority of cases, you know, that
16 that -- that would be true in a lot of, a lot of cases.

17 **Q.** And, and with respect to illegal opioids like heroin
18 and illicit fentanyl, it means criminal traffickers or
19 criminal actors have trafficked the drugs into the community
20 and then sold them to end-users; correct?

21 **A.** That would be true for prescription opioids as well in
22 many cases.

23 **Q.** Right.

24 **A.** So any, any way that the illegal route gets into the
25 community, what -- regardless of what the opioid is, it

1 would be through a trafficking mechanism.

2 **Q.** Right. So your point is there may also be legal
3 prescriptions that were issued at some point legally, but
4 they've then been trafficked into a local area by drug
5 traffickers; right?

6 **A.** That can occur.

7 **Q.** And, so, when you -- oh, when you opined last week that
8 exposure to opioids causes harm, you mean that the ingestion
9 of opioids into a person's body can cause harm; right?

10 **A.** There are other types of harms that are outlined in my
11 report that can occur to communities when rates of opioid
12 use are high; for example, to children and families.

13 **Q.** But those are ripple effects that begin with somebody
14 ingesting opioids into their body; correct?

15 **A.** Yes.

16 **Q.** Now, you testified on Friday that it's very difficult
17 to acquire opioid use disorder if you've never been exposed
18 to opioids, almost a truism, right, if nobody -- if somebody
19 has never used an opioid, they're unlikely to develop opioid
20 use exposure; correct?

21 **A.** It would be impossible. It's a, it's a necessary cause
22 of opioid use disorder.

23 **Q.** So, Dr. Keyes, I believe last week in your testimony
24 you spoke about an over-supply of opioids; correct?

25 **A.** Yes.

1 **Q.** And you also mentioned that in your report. You talked
2 about this idea that in your view, there was an over-supply
3 of opioids in Cabell/Huntington; correct?

4 **A.** Yes.

5 **Q.** And you recognize, I take it, that there are legitimate
6 medical needs for opioids; correct?

7 **A.** You know, as a, as a general matter, I think the
8 legitimacy of opioids for any particular condition is one
9 that has been controversial for a lot of different
10 conditions.

11 **Q.** But you understand that opioids are a legitimate
12 medicine that are used for legitimate purposes to treat
13 pain; correct?

14 **A.** It would really depend on what the purpose is. There
15 are many applications of opioids that have been argued were
16 inappropriate.

17 **Q.** So you're not aware of any legitimate uses for opioids
18 to treat pain?

19 **A.** Certainly, opioids relieve pain, and certainly there
20 are circumstances in which an opioid would be an appropriate
21 medication, particularly for end-of-life pain, for example,
22 and some acute conditions for which opioids are prescribed
23 for a short-term. But for a large majority of purposes for
24 which opioids are prescribed, there's literature that has
25 been developed calling into question their efficacy.

1 Q. Well, do you believe that when used as prescribed under
2 medical supervision, opioid analgesics are effective and
3 used as standard practice in managing pain?

4 A. I believe you're quoting the American Journal of Public
5 Health article that I published in 2013. Right?

6 Q. You have a good memory.

7 A. Thank you very much. You know, I think that that
8 sentence in that paper, the paper wasn't about the efficacy
9 of opioids. And certainly in 2013 a lot of us had a broader
10 view of opioids I guess I would say.

11 But the two citations I think that are, are made to
12 that sentence, if you go to those citations, I think it
13 provides a broader context for that particular sentence.

14 Q. Let me show you that document then.

15 A. Sure.

16 MR. HESTER: Your Honor, may I approach?

17 THE COURT: Yes.

18 BY MR. HESTER:

19 Q. You probably remember this one.

20 Dr. Keyes, I've handed you a document marked as
21 Defendants' West Virginia Exhibit 2516. And the title is
22 "Understanding the Rural-Urban Differences in Non-Medical
23 Prescription Opioid Use and Abuse in the United States."

24 Do you see that?

25 A. Yes, I do.

1 Q. And this is an article you wrote; correct?

2 A. I was the first author, yes.

3 Q. So there were several authors, but you were one of the
4 authors of this paper?

5 A. I was.

6 Q. And let me ask you to look at Page 3, and I'm using the
7 small numbers in the left-hand corner. And I think we're
8 together on this, but I just wanted to make sure the record
9 is clear.

10 So there's -- under the heading "Self-medicating for
11 Pain," there's a statement that says, "When used as
12 prescribed under medical supervision, opioid analgesics are
13 effective and used as standard practice in managing acute
14 and chronic pain."

15 Do you see that?

16 A. I do.

17 Q. And that was a true statement at the time you wrote it;
18 correct?

19 A. Well, I think I would just provide a little more
20 context to that statement. I think -- if I were to write it
21 today, I certainly -- and I think most epidemiologists would
22 not have such a blanket statement about opioid prescribing
23 certainly in 2013. I think many of us were affected by some
24 of the same inappropriate marketing and misleading
25 advertising and statements by industry that many doctors

1 were as well.

2 But I think if you actually go to the two references
3 that I've cited there, what the underlying references
4 suggest is that for a lot of purposes for which opioids were
5 prescribed, although prescribing increased, there was very
6 little evidence for efficacy.

7 So I think that that sentence is inartfully worded I
8 would say. And if I were to write it again today, I would
9 certainly provide a lot more context that would be
10 consistent with the actual science that is cited in those
11 underlying citations.

12 MR. HESTER: Your Honor, I would move to strike
13 the answer as not responsive. I asked Dr. Keyes whether it
14 was accurate at the time she wrote it, and she's now
15 answered a different question.

16 THE COURT: Well, I'll grant the motion to strike.
17 You need to answer the precise question, Dr. Keyes.

18 MR. FARRELL: Judge, I'd like to at least --

19 THE COURT: Mr. Farrell.

20 MR. FARRELL: Yes, sir. I'd like to say that I
21 oppose his motion to strike and note it for the record,
22 please.

23 THE COURT: Well, she can explain her answer
24 and -- but I believe she went a little beyond that. So your
25 objection is noted, Mr. Farrell.

1 MR. FARRELL: Thank you.

2 BY MR. HESTER:

3 Q. So, Dr. Keyes, I just wanted to clarify that at the
4 time you wrote this, you believed this to be a true
5 statement; correct?

6 A. At the time that I wrote that, I, I -- yes, I believed
7 it to be -- I believed it to be a statement that was based
8 in the literature.

9 Q. And you have not undertaken to determine the supply of
10 opioids that are needed to meet medical needs in West
11 Virginia, have you?

12 A. I believe that that type of information is in my
13 report.

14 MR. HESTER: Let me pull up, please, Dr. Keyes'
15 deposition from this case at pages -- at Page 126, lines 6
16 to 10.

17 BY MR. HESTER:

18 Q. Dr. Keyes, first let me ask you, do you remember
19 being deposed in this litigation?

20 MR. FARRELL: Objection, Your Honor. I'm not
21 quite sure that impeachment has been established at this
22 point in time.

23 THE COURT: Well, we don't know yet.

24 MR. FARRELL: So before we put up transcripts of
25 other proceedings, I think the foundation has not yet been

1 laid to bring up her prior testimony.

2 MR. HESTER: Your Honor, I asked her a question
3 and, and now I have a deposition excerpt that I believe the
4 response is the same question that she answered during her
5 deposition.

6 THE COURT: Mr. Ackerman.

7 MR. ACKERMAN: Yeah, but the problem is that
8 counsel hasn't established that yet. He asked a question
9 and then went straight to the deposition which is not the
10 proper method of establishing --

11 THE COURT: Well, you got an answer from her,
12 didn't you, Mr. Hester?

13 MR. HESTER: I did get an answer.

14 THE COURT: Overruled. Go ahead.

15 BY MR. HESTER:

16 Q. So, Dr. Keyes, you recall being deposed in this
17 litigation; correct?

18 A. I do.

19 Q. And you and I had the pleasure of going through that
20 deposition; correct?

21 A. Yes.

22 Q. And, so, let me ask you to look at Page 126, line 6.

23 And, so, my question to you was, "So you've not untaken
24 any evaluation of how many pills are needed in
25 Cabell/Huntington?" That was my question.

1 And your answer was, "I -- no, I have not taken -- I've
2 not undertaken that."

3 Do you see that?

4 MR. ACKERMAN: Your Honor, I want to voice an
5 objection because the question on this deposition is
6 different than the question that was asked of the witness.
7 And that's exactly why we need to establish foundation
8 before we bring up other testimony.

9 THE COURT: Well, I think it's close enough and
10 I'll overrule the objection.

11 Go ahead, Mr. Hester.

12 BY MR. HESTER:

13 **Q.** And your answer was, "I have not taken -- I have
14 not undertaken that." Do you see that?

15 **A.** I do.

16 **Q.** And was that a correct statement when you gave it?

17 **A.** No, I, I have not -- myself have not undertaken any
18 statistical evaluation. I have reviewed the literature
19 which is what is in the report.

20 **Q.** But my question to you in that deposition was you have
21 not undertaken any evaluation of how many pills are needed
22 in Cabell County. And your answer was, "No, I have not
23 undertaken that."

24 Is that correct when you said it?

25 **A.** That's what the deposition says. I think my

1 interpretation of the question was whether I had undertaken
2 a statistical evaluation.

3 **Q.** Well, Dr. Keyes, I'm asking was your testimony accurate
4 when you gave it in your deposition?

5 **A.** Yes. I have not undertaken a statistical evaluation,
6 although I have reviewed the literature. So I just want to,
7 I guess, clarify my interpretation of the question.

8 **Q.** And you have not undertaken any analysis of the pain
9 needs specifically in Cabell/Huntington, have you?

10 **A.** No, I have not.

11 **Q.** So you don't know the level of supply needed to meet
12 the pain needs of Cabell/Huntington; correct?

13 **A.** I would say that the, the consensus of the literature
14 that I cite in the report is that in terms of the opioid
15 needs in the community, the pre-opioid epidemic levels were
16 the levels that should be considered as, as meeting the pain
17 needs of the community.

18 MR. HESTER: Your Honor, I move to strike as
19 nonresponsive.

20 THE COURT: I grant the motion to strike. Go
21 ahead.

22 BY MR. HESTER:

23 **Q.** So, Dr. Keyes, you do not know the level of supply
24 of prescription opioids needed to meet the pain needs of
25 Cabell/Huntington; correct?

1 **A.** The -- I, I do know. I have an opinion about that.

2 **Q.** Well, you've not undertaken any analysis for the pain
3 needs in Cabell/Huntington; correct? You just said that.

4 **A.** Correct.

5 **Q.** And, so, you don't know the level of supply of need to
6 meet those pain needs because you don't know the level of
7 pain needs in the community; correct?

8 **A.** Again, I could point to literature to inform the answer
9 to that question.

10 **Q.** But you haven't undertaken that analysis of pain needs
11 in Cabell/Huntington; correct?

12 **A.** That's right.

13 **Q.** Now, Dr. Keyes, you prepared a 54-page, single-spaced
14 report in this case; right?

15 **A.** I, I trust that that's correct.

16 **Q.** I think that's the right count. In small font too I
17 would add; correct?

18 **A.** I suppose it was small.

19 **Q.** You did not evaluate any specific distributors in your
20 report; correct?

21 **A.** The information that is included in the report includes
22 aggregated data across distributors, although I did not
23 evaluate any specific company by name.

24 **Q.** And your report does not mention McKesson, Cardinal, or
25 ABDC at all, does it?

1 **A.** It does not.

2 **Q.** And you did not review any documents relating to the
3 distributors' individual activities, did you?

4 **A.** I, I don't believe -- I'm just trying to remember what
5 is included in the ARCOS data. I'm not sure -- I do believe
6 there's some information on specific distributors, although
7 the information in my report is in the aggregate.

8 **Q.** Dr. Keyes, I was asking about documents. You did not
9 review any documents relating to the distributors'
10 individual activities, did you?

11 **A.** I believe I reviewed some documents about market share
12 generally.

13 MR. HESTER: May we bring up Dr. Keyes'
14 deposition, please, from this case, Page 301.

15 BY MR. HESTER:

16 **Q.** And, Dr. Keys, again, you recall being deposed in
17 this case; correct?

18 **A.** I do.

19 **Q.** Let me ask you to look at Page 301, line 1.

20 My question to you was, "But you've not reviewed
21 specific documents relating -- related to their individual
22 activities?"

23 Do you see that question?

24 MR. FARRELL: Objection, Your Honor. So, again,
25 his first question is materially different than the question

1 on the screen. So I would object to the first question as
2 being vague. And I would object to the use of the
3 transcript as being improper impeachment.

4 THE COURT: Overruled.

5 Go ahead, Mr. Hester.

6 BY MR. HESTER:

7 Q. So my question was, "But you've not reviewed
8 specific documents related to their individual
9 activities?"

10 Do you see that question?

11 A. I do.

12 Q. And your answer was, "Generally, no." Was that your
13 answer?

14 A. That's what's written.

15 Q. Well, and is that what you answered, Dr. Keyes?

16 A. That's what I answered in the deposition.

17 Q. And was that answer true and correct when you gave it?

18 A. Yes. As I've said, as I'm thinking it over, you know,
19 I did see some documents related to market share. So I
20 think the "generally, no" statement leaves some room for,
21 yes, I have seen some documents related to market share.

22 Q. You did not assess any individual distributor's
23 contribution to opioid supply relative to other
24 distributors; correct?

25 A. I have not.

1 **Q.** And as part of your methodology, you did not evaluate
2 how many opioids that McKesson, Cardinal, or ABDC
3 individually had shipped into Huntington and Cabell County;
4 correct?

5 **A.** That's correct.

6 **Q.** Your report, in fact, does not make any mention as to
7 how many opioids McKesson, Cardinal, or ABDC individually
8 shipped into Huntington or Cabell County; correct?

9 **A.** That's right. It's the total number of shipments.

10 **Q.** And you don't know the respective market shares of
11 McKesson, ABDC, and Cardinal vis-à-vis their distributions
12 into Cabell and Huntington; correct?

13 **A.** As I mentioned, I have reviewed documents related to
14 that, although that's not my area and it is not in my
15 report.

16 **Q.** And you don't know what their respective market shares
17 are for their distribution of opioids into Cabell and
18 Huntington County; correct?

19 **A.** Not off the top of my head.

20 **Q.** I'm sorry, Cabell County and Huntington. Sorry. You
21 don't --

22 **A.** Not sitting here today.

23 **Q.** And you don't have any knowledge in relation to the
24 operations of McKesson, Cardinal, or ABDC in Cabell County
25 and Huntington; correct?

1 **A.** Can you clarify what you mean by knowledge?

2 **Q.** Do you have any knowledge in relation to the operations
3 specifically of McKesson, ABDC, or Cardinal in Cabell County
4 and Huntington?

5 MR. ACKERMAN: Objection, vague.

6 THE COURT: Overruled.

7 THE WITNESS: I'm, I'm generally familiar with the
8 activities of distributors, but I have not reviewed any
9 specific material related to operations in Cabell and
10 Huntington that have -- that were in my report or that
11 informed the opinions that I've given in the report.

12 BY MR. HESTER:

13 **Q.** So you didn't discuss those factors in your report;
14 correct?

15 **A.** That's -- well, I'm sorry. Can you -- the question is
16 the --

17 **Q.** Do you have any knowledge in relation to the operations
18 of McKesson, Cardinal, or ABDC specifically in Cabell County
19 and Huntington?

20 **A.** In the report I discussed general distribution
21 operations, but not with regard to any company specifically.

22 **Q.** And, so, your answer is "no;" correct?

23 **A.** Correct.

24 **Q.** You did not review the content of any distributor
25 Suspicious Order Monitoring Program for purposes of your

1 report in this case; correct?

2 **A.** That's correct.

3 **Q.** You did not review any of the orders that were made by
4 pharmacies in Huntington or Cabell County for prescription
5 opioids; correct?

6 **A.** No, I did not review any specific orders.

7 **Q.** And you're not offering an opinion on how many opioids
8 McKesson, Cardinal, or ABDC shipped to any specific pharmacy
9 in Huntington or Cabell County; correct?

10 **A.** Not a specific pharmacy, no.

11 **Q.** And you cannot identify a single prescription opioid
12 that was distributed by the defendants in Cabell County or
13 Huntington that in your opinion should have been
14 investigated and not shipped? That's not something you've
15 done; correct?

16 **A.** That's not in, in the lens of epidemiology. We
17 typically don't look at individual prescriptions.

18 **Q.** And you're not aware of any occasion where McKesson,
19 ABDC, or Cardinal shipped opioids that exceeded their
20 permissible quotas set by the DEA; correct?

21 **A.** I have not looked at specific quota levels and
22 shipments that have exceeded them.

23 **Q.** You're not aware of any evidence that McKesson,
24 Cardinal, or ABDC shipped pills into Huntington or Cabell
25 County that exceeded the levels doctors had prescribed;

1 correct?

2 **A.** I, I have not reviewed evidence related to specific
3 shipments.

4 **Q.** And, so, you're not aware of any evidence that they
5 shipped pills into Huntington or Cabell County that exceeded
6 the levels prescribed by doctors; correct?

7 **A.** Right. That is not something in my report.

8 **Q.** You've published, I believe you said last week, 306
9 peer-reviewed articles; is that correct?

10 **A.** Yes.

11 **Q.** And about 35 to 40 of those relate specifically to
12 opioid use and opioid harms; is that correct?

13 **A.** Yes.

14 **Q.** And some of them address the causes of the opioid
15 crisis; right?

16 **A.** That's right.

17 **Q.** None of your articles that you've written on the opioid
18 crisis or opioid harms refer to McKesson as a cause of the
19 opioid crisis; correct?

20 **A.** It refers to over-supply and distribution more
21 generally.

22 **Q.** Can you answer --

23 **A.** I have not named McKesson in any of those articles.

24 **Q.** So none of your articles refer to McKesson as a cause
25 of the opioid crisis; correct?

1 **A.** In the sense that McKesson is a distributor and the
2 distribution of opioids are identified as a cause, I think
3 it's fair to say that I have identified McKesson.

4 MR. HESTER: Your Honor, I move to strike as not
5 responsive.

6 THE COURT: Well, I'll overrule that. I think
7 that was responsive.

8 BY MR. HESTER:

9 **Q.** None of your articles refers to distributors
10 collectively as a cause of the opioid crisis; correct?

11 **A.** No, that's incorrect. I talk about the over-supply of
12 prescription opioids.

13 **Q.** I'm talking about distributors collectively. I'm not
14 talking about over-supply. My question is none of your
15 articles refers to distributors collectively as a cause of
16 the opioid crisis; correct?

17 MR. ACKERMAN: Objection, asked and answered.

18 THE COURT: Overruled.

19 THE WITNESS: I do talk about distribution of
20 opioids as a cause of the opioid crisis. And, therefore,
21 the contributors to distribution would be the cause of the
22 distribution. It doesn't arise magically.

23 MR. HESTER: Let me ask to pull up the *Frye*
24 transcript from New York, Page 153.

25 BY MR. HESTER:

1 Q. Dr. Keyes, do you remember testifying in a *Frye*
2 hearing in New York?

3 A. I do.

4 Q. I believe you mentioned that last week; correct?

5 A. Yes.

6 Q. And let me show you Page 153 of the transcript, line
7 17.

8 And there was a question asked, "Is there a publication
9 you can point us to where you say that in that publication
10 that distributors as a class caused the opioid crisis?"

11 And your answer was, "Not back then, no."

12 Do you see that?

13 MR. ACKERMAN: Objection, Your Honor. This isn't
14 the same question that was asked. Frankly, if you look at
15 the immediate preceding question on this transcript, it has
16 the exact same answer that the witness just gave. This is
17 improper impeachment, Your Honor.

18 MR. HESTER: I object to the speaking objection,
19 Your Honor. If the objection is improper impeachment, that
20 should be the objection.

21 THE COURT: Well, I'm going to overrule the
22 objection.

23 You can go ahead, Mr. Hester.

24 BY MR. HESTER:

25 Q. Was that, was that answer that you gave, Dr. Keyes,

1 accurate and true when you gave it?

2 **A.** This is a different question.

3 **Q.** I'm asking whether the answer that you gave to the
4 question on the transcript was true and accurate when you
5 gave it.

6 **A.** Yes.

7 **Q.** All right. Dr. Keyes, let's talk about a few of your
8 articles in a little more detail.

9 MR. HESTER: May I approach, Your Honor?

10 THE COURT: Yes.

11 BY MR. HESTER:

12 **Q.** Dr. Keyes, I've handed you a document marked as
13 MC-WV-01806. And on its face it appears to be an
14 article, "A Critical Review of the Social and Behavioral
15 Contributions to the Overdose Epidemic."

16 Dr. Keyes, I take it you're familiar with this article?

17 **A.** I am.

18 **Q.** And you're one of the authors of it; correct?

19 **A.** Yes.

20 **Q.** And if you look at Page 12 and, again, working off of
21 the small numbers at the bottom, and this is under the
22 heading for "Author Contributions" there's a statement,
23 "K.M.K. provided feedback on the initial structure of the
24 paper, wrote sections, and critically reviewed and edited
25 multiple versions of the manuscript."

1 Do you see that?

2 **A.** I do.

3 **Q.** And I take it K.M.K. is a reference to you?

4 **A.** Yes.

5 **Q.** So that's a fair description of what you did in
6 relation to this article?

7 **A.** Yes.

8 **Q.** So this article was originally published as a review in
9 advance on November 30, 2020; correct?

10 **A.** Yes.

11 **Q.** And then it was published in its final form in the
12 Annual Review of Public Health in April, 2021; is that
13 correct?

14 **A.** Yes.

15 **Q.** And, so, it was published after you had been retained
16 as an expert in this case; correct?

17 **A.** Yes.

18 **Q.** And it was published after you wrote your expert
19 report; correct?

20 **A.** The expert report for --

21 **Q.** For this litigation.

22 **A.** Yes.

23 **Q.** And it was published after you sat for your deposition
24 in this case; correct?

25 **A.** I don't remember the exact timing, but I trust that --

1 Q. I think it was September of last year that we had the
2 pleasure. Does that sound about right?

3 A. That sounds right.

4 Q. So this paper went through a process of peer-review; is
5 that correct?

6 A. Yes.

7 Q. And what does peer-review mean? Can you explain just
8 very briefly what peer-review means?

9 A. Sure. When you submit a journal -- an article to a
10 journal, the editor of the journal will decide whether it
11 merits further consideration. And if it does, they will
12 invite, you know, other scientists who have expertise in
13 this area to read the paper and say whether it has
14 scientific merit.

15 Q. And, so, there, there are peers that provide input on
16 the article. And then that peer-review process ensures the
17 legitimacy or the accuracy of the article? Is that the
18 concept?

19 A. Well, I wouldn't say that it ensures accuracy or
20 legitimacy. It's really more of, you know, having your
21 peers read the paper and, and provide an assessment to the
22 editor really of whether the paper is, is scientifically
23 meritorious of publication.

24 Q. And is it a fair statement that peer-review is a
25 meaningful step in publishing an article, that that means

1 something about the, the, the article?

2 **A.** It's certainly a requirement of most journals that an
3 article is, is identified as meritorious by your scientific
4 peers.

5 **Q.** And if the peers were to say that it was not
6 meritorious or lacked weight or had problems, would that
7 cause the article either to be changed or not published?

8 **A.** Ultimately, the decision rests with the editor.
9 Certainly, editors listen to the feedback of peer-reviewers.
10 And, so, if your peers -- if the peer-reviewers all said,
11 you know, this article is not scientifically meritorious,
12 then an editor would likely not accept the paper in the
13 journal.

14 **Q.** So let me ask you to look at Page 3 of this article,
15 please. And, again, I'm working off of the small numbers at
16 the bottom left.

17 I wanted to focus you under the heading for "Supply
18 Drivers of the Opioid -- of the Overdose Epidemic." And
19 then there's a subheading for "The Prescription Opioid
20 Supply: Chronic Pain and Opioid Prescribing."

21 Do you see that?

22 **A.** I do.

23 **Q.** And there's a first sentence under that heading that
24 reads, "The supply-side roots of the overdose epidemic in
25 the United States lie at the intersection of two social and

1 behavioral forces that, together, led to the proliferation
2 of opioid prescribing in the 1990s, especially for
3 non-cancer acute and chronic pain conditions."

4 Do you see that?

5 **A.** I do.

6 **Q.** Is that a true statement?

7 **A.** I believe that's an accurate representation of the
8 literature.

9 **Q.** And it goes on to say, "The first force was a shift in
10 treatment approaches for chronic non-cancer pain, including
11 a campaign by professional pain societies and the U.S. Joint
12 Commission, the nation's largest accrediting body for
13 healthcare organizations, to consider pain as the fifth
14 vital sign and to improve the quality of care for chronic
15 pain."

16 Do you see that?

17 **A.** I do.

18 **Q.** And that's a true statement; correct?

19 **A.** I think that that accurately represents the literature.

20 **Q.** Then let me point you to the next paragraph which
21 begins, "The second related force involved the
22 pharmaceutical industry's concerted efforts to advocate for
23 the long-term use of opioids as a safe, non-addictive,
24 effective, and humane alternative to treat non-cancer pain."

25 Do you see that?

1 **A.** I do.

2 **Q.** And then it goes on a few sentences later to say, "In
3 1996-2002, Purdue Pharma provided funds for educational
4 campaigns supporting the use of opioids to treat chronic
5 non-cancer pain and supported efforts by pain professional
6 societies, the U.S. Joint Commission, and the Federation of
7 State Medical Boards to advocate for the use of opioids to
8 treat pain."

9 Do you see that?

10 **A.** Yes.

11 **Q.** And is that a true statement?

12 **A.** I believe it reflects the literature.

13 **Q.** Let me point you to Page 4, please. Just before the
14 heading for the illegal opioid supply, there's a statement,
15 "The expansion of PO supply --" and I take it PO means
16 prescription opioids; right?

17 **A.** That's right.

18 **Q.** "The expansion of PO supply increased opioid-related
19 harm through several pathways affecting both individuals who
20 initially used opioids as prescribed but developed impaired
21 control over use and individuals who used non-medically and
22 obtained opioid prescriptions through family, friends, or an
23 illicit diversion source."

24 Do you see that?

25 **A.** I do.

1 Q. And that's a true statement; correct?

2 A. It reflects the literature, yes.

3 Q. And, so, in this sentence, there's a reference to using
4 opioids non-medically. And that means opioids not being
5 used pursuant to a doctor's correction [sic]; correct? I'm
6 sorry. Doctor's direction; correct?

7 A. Yes.

8 Q. And, for instance, using opioids without a prescription
9 is a form of non-medical use; correct?

10 A. That's right.

11 Q. Stealing opioids from somebody's medicine cabinet and
12 then ingesting them is a form of non-medical use; correct?

13 A. It is.

14 Q. Buying opioids from a drug trafficker and ingesting
15 them is a form of non-medical use; correct?

16 A. Yes.

17 Q. Also, taking pills more frequently or for a longer
18 period of time than prescribed is also a form of non-medical
19 use; correct?

20 A. That's right.

21 Q. The reference here to -- in this sentence we're looking
22 at just before the next paragraph where it says that opioids
23 were obtained through family or friends, is that -- I take
24 it the reference there means someone had a legitimate
25 prescription and then gave or sold them to family or

1 friends; correct?

2 **A.** Not necessarily. I mean, a lot of people can obtain
3 prescription opioids through non-medical sources and give
4 them to family or friends or sell them to family or friends
5 as well.

6 **Q.** Well, I wanted to ask about the idea that individuals
7 who used non-medically obtained opioid prescriptions through
8 family or friends. And, so, is the point there that the
9 family or friends may have had a legitimate prescription and
10 then gave those pills or sold them to someone else who used
11 it non-medically?

12 **A.** That could happen. Certainly, one source of opioids is
13 a family or friend who received a prescription for opioids
14 and didn't finish the bottle or, you know -- but, also, the
15 family or friend could have themselves obtained the
16 prescription opioids non-medically.

17 So the literature that forms the basis of that
18 statement usually asks people, "Where do you obtain your
19 opioids?" And people say family or friends, but they don't
20 specify where the family or friend got the medication.

21 **Q.** So your point is there might be one set of
22 circumstances where a family member had a prescription but
23 didn't use all the opioids and then either gave or sold them
24 to somebody else. That's one scenario; correct?

25 **A.** That is one scenario.

1 **Q.** And another scenario might be that a family member him
2 or herself had obtained opioids illegitimately and then
3 handed them over to somebody else; correct?

4 **A.** Yes. And I think a third scenario is that people
5 obtain opioids from a medical source where the prescriber is
6 not prescribing for a legitimate medical need for example.

7 **Q.** So there's a reference in that same sentence we were
8 just looking at to individuals who used non-medically and
9 obtained opioid prescriptions from an illicit diversion
10 source. Do you see that?

11 **A.** Yes.

12 **Q.** And does the reference to an illicit diversion source
13 mean some sort of drug trafficker or someone who's selling
14 the opioids?

15 **A.** That's one possibility for an illicit diversion source.

16 **Q.** But this is diversion after the prescriptions have --
17 I'm sorry. Let me strike that and start over. This is not
18 diversion in the closed system for controlled substances;
19 correct?

20 **A.** The definition of diversion that I used, just to -- if
21 I could answer your question with a little bit of context, I
22 hope that's okay.

23 The definition of diversion that I use in the report is
24 any opioids that are used by someone who they were not
25 prescribed for. So an illicit diversion source would

1 include any use of opioids by someone who they were not
2 prescribed for which would include opioids that arrived
3 through the closed system.

4 **Q.** But it could -- but the point would be when you're
5 talking here about an illicit diversion source, you're
6 talking about an illicit diversion source after the pills
7 are outside of a pharmacy; correct?

8 **A.** Again, I, I don't know how -- exactly how to answer
9 that because the diversion definition is the use of an
10 opioid by someone for whom it is not prescribed.

11 So an illicit diversion source would be any source that
12 got a prescription to someone for whom it is not prescribed.
13 And that would include a number of different mechanisms,
14 including a bottle that left the pharmacy and got into the
15 hands of someone it wasn't prescribed for. But it would
16 also include a lot of other potential diversion mechanisms.

17 **Q.** A very common one that you've seen and you discuss in
18 your report is the scenario where the pills are prescribed
19 to somebody. They're -- it's a legitimate prescription.
20 But then they later end up into illicit channels. Correct?
21 That's a very common pattern you've seen?

22 **A.** There is a common pattern whereby people have unused
23 medication from an opioid prescription. I would say that is
24 common. But there are other mechanisms as well.

25 **Q.** Let me ask you to look at Page 2, please.

1 In the middle of the second paragraph there's a
2 statement, "Heroin use and related harms increased in the
3 mid 2000s surpassing prescription opioids as a cause of
4 opioid-related overdoses in 2015."

5 Do you see that?

6 **A.** I do.

7 **Q.** And that's a true statement; correct?

8 **A.** Yes, based on the CDC data.

9 **Q.** And then let me ask you to look at Page 4 again.

10 There's -- about three sentences in under illegal
11 opioid supply, in that paragraph there's a sentence that
12 reads, "While state restrictions on prescription opioids may
13 have increased the risks of transition to heroin use among
14 people with a dependence on prescription opioids, shifts in
15 the heroin market also likely played an important role."

16 Do you see that?

17 **A.** I do.

18 **Q.** And that's a true statement; correct?

19 **A.** Yes, based on the literature.

20 **Q.** In that same paragraph it says, it says, "In the mid
21 1990s the U.S. supply of South American heroin increased
22 substantially while the fraction of the market controlled by
23 the Asian heroin decreased dramatically."

24 Do you see that?

25 **A.** I do.

1 Q. And that's a true statement; correct?

2 A. That's my understanding of the literature.

3 Q. And then it goes on to say, "Mexican black tar heroin
4 dominated the West Coast market while Colombian heroin
5 dominated the East Coast."

6 Do you see that?

7 A. I do.

8 Q. And that's a true statement; correct?

9 A. Again, that's my understanding of the literature.

10 Q. And the reference to Colombian heroin there, that's to
11 a white powder heroin; correct?

12 A. Yes.

13 Q. And then it goes on to say, "Abundant supply, low
14 price, and high purity of the Colombian heroin reduced the
15 price per gram of pure heroin."

16 Do you see that?

17 A. I do.

18 Q. And that's a true statement; correct?

19 A. Based on my read of the literature.

20 Q. And then it goes on to say, "In 2013 the illegal opioid
21 market shifted again with the introduction of fentanyl,
22 often mixed with heroin or sold as counterfeit oxycodone and
23 benzodiazepines."

24 Do you see that?

25 A. I do.

1 Q. And that's a true statement; correct?

2 A. That's my understanding of the literature.

3 Q. It goes on to say that, "Fentanyl is cheaper to
4 produce. The wholesale price is one-tenth of heroin's price
5 by weight, and is 30 to 40 times stronger than heroin, so
6 that a comparable dose would be 1/300 to 1/400 of the
7 wholesale price of heroin."

8 Do you see that?

9 A. Yes.

10 Q. And that's a true statement; correct?

11 A. Based on my read of the literature.

12 Q. There's a reference here to counterfeit oxycodone. Do
13 you see that?

14 A. Oh, yes.

15 Q. And that reference means fentanyl being sold as a
16 counterfeit prescription opioid perhaps mixed with some
17 filler; correct?

18 A. Can you say that question again?

19 Q. Yeah, sorry. I didn't ask that very well. When it
20 refers to counterfeit oxycodone, that's referring to a
21 counterfeit prescription pill; correct?

22 A. Yes.

23 Q. And the counterfeiting is done by the drug dealer; is
24 that correct?

25 A. My -- that's my understanding. They are manufactured

1 outside of the pharmaceutical company.

2 **Q.** And the counterfeit pill typically includes some
3 fentanyl; is that correct?

4 **A.** It could. That's what that sentence is saying.

5 **Q.** And, and presumably it wouldn't be a full-size pill all
6 of fentanyl. It would have some filler or something else as
7 part of the counterfeit?

8 **A.** It's possible.

9 **Q.** If it were a full-size pill with fentanyl, it would
10 kill somebody almost immediately; correct?

11 **A.** It would depend on the amount of fentanyl and the
12 tolerance of the individual taking it.

13 **Q.** If you look back at Page 2 again, again in that top
14 section under "National Trends," there's a statement that
15 says, "Overdoses involving synthetic opioids other than
16 methadone became the predominant opioid cause of death."

17 Do you see that?

18 **A.** Yes.

19 **Q.** And that's a true statement; correct?

20 **A.** Yes, that is what the data show.

21 **Q.** And synthetic opioids there as it's used is referring
22 primarily to illicit fentanyl; correct?

23 **A.** In terms of what's causing the increase in overdoses?

24 **Q.** Yes.

25 **A.** Yes, that is what the consensus is.

1 Q. It could also be referring to carfentanil; correct?

2 A. Yes.

3 Q. And you're aware that both illicit fentanyl and
4 carfentanil are much more potent than heroin; correct?

5 A. Yes.

6 Q. In that -- in the next paragraph it says, "Overdose
7 deaths involving stimulants such as cocaine and
8 methamphetamine began to increase rapidly in 2015 due in
9 large part to adulteration of those substances with
10 synthetic opioids."

11 Do you see that?

12 A. I do.

13 Q. And that's a true statement; correct?

14 A. That's what the literature shows.

15 Q. And when it says "adulteration" there, that's referring
16 to something that's being done by the drug dealer to cut the
17 heroin or to create a counterfeit tablet; correct?

18 A. Yes.

19 Q. And, so, when that occurs -- when, when the heroin is
20 being cut or a pill is being counterfeited, the drug dealers
21 are, are in effect cheating the user by adulterating the
22 heroin with fentanyl; correct?

23 A. They're -- I'm sorry. They're cheating the user?

24 Q. Cheating the user because they're not giving the
25 user -- if the user thinks he or she is buying heroin and

1 they get heroin adulterated with fentanyl, that's not what
2 the user expects; right?

3 **A.** It would really depend on the, on the particular user
4 and the drug market. There are some drug users who prefer
5 fentanyl.

6 **Q.** You're aware that many drug users who are taking heroin
7 are unaware that the heroin has been adulterated with
8 fentanyl; correct?

9 **A.** There are many users who are unaware. But there are
10 users who, who prefer the potency of a strong opioid.

11 **Q.** But for the users who are unaware that heroin is being
12 cut with fentanyl, they may experience an overdose without
13 knowing the risk they were taking because they weren't aware
14 that the heroin had been cut with fentanyl; correct?

15 **A.** If -- I mean, that's -- it's sort of tautological. If
16 the user is unaware, then the user would not know that there
17 is fentanyl by definition of being unaware. And what I'm
18 saying is that many users are aware.

19 **Q.** But the user who is unaware would also, therefore, not
20 know the risk that he or she is taking by ingesting heroin
21 that's been adulterated with fentanyl; correct?

22 **A.** I would say any user who's not aware of the potency of
23 the drugs that they're taking is taking a risk.

24 MR. FARRELL: Excuse me, Mr. Hester. I got lost
25 there. Can you tell me the page number?

1 MR. HESTER: Sorry, Paul. It was Page 2.

2 MR. FARRELL: I'm sorry. I missed it.

3 BY MR. HESTER:

4 Q. All right, Dr. Keyes, you can put that one aside
5 for now. We'll look at another one.

6 MR. HESTER: May I approach, Your Honor?

7 THE COURT: Yes.

8 BY MR. HESTER:

9 Q. Dr. Keyes, we've handed you what's been marked as
10 Defendants' West Virginia Exhibit 2518. On its face it
11 has a heading "Prescription Opioid Use Disorder and
12 Heroin Use Among Youth Non-Medical Prescription Opioid
13 Users from 2002 to 2014."

14 Do you see that?

15 A. I do.

16 Q. And I take it this is an article that -- for which you
17 were one of the co-authors; correct?

18 A. Yes.

19 Q. And it was published in February of 2017?

20 A. Yes.

21 Q. And in this article you set forth causes of the
22 increasing trend in prescription opioid use disorder that
23 had been observed in young adults at that time; is that
24 correct?

25 A. This article -- there's no abstract that is produced

1 with this. I'm not sure if that can be provided as well.
2 But this article examined changes in prevalence of heroin
3 use among non-medical prescription opioid users. I don't
4 believe it assessed risk factors or provided a causal
5 analysis.

6 **Q.** Let me look with you at Page 7 of the article. Again,
7 we're using the small numbers on the left.

8 There's a -- this is a paragraph that begins, "Although
9 our study does not assess underlying causes, the increasing
10 trend in prescription opioid use disorder observed in young
11 adults might be at least partially explained by historical
12 factors described elsewhere in the literature."

13 Do you see that?

14 **A.** I do.

15 **Q.** And, so, what -- when you're referring to the
16 literature there -- I think I've learned over time this is
17 one of the things epidemiologists do is they study
18 literature and draw conclusions from it; correct?

19 **A.** Yes.

20 **Q.** And that's what you're doing here. You're summarizing
21 a body of literature by referring back to it; correct?

22 **A.** I don't think this summarizes the totality of the
23 literature. I think this points to a number of underlying
24 potential explanations, but it doesn't assess or review the
25 literature for the validity of those explanations.

1 Q. But it did pull out propositions that had been found in
2 the literature I take it; correct?

3 A. Right. This is typically what's done in kind of
4 discussion sections as we look to the body of literature and
5 we say, okay, what are the potential explanations for the
6 trends that we're seeing and what research program would we
7 need to initiate in order to provide the kind of causal
8 analysis on those factors that I think you're suggesting.

9 Q. So when you refer here to the historical factors
10 described elsewhere in the literature, you're referring to
11 other papers that had previously identified these various
12 factors that are discussed as ones that might be
13 contributing to prescription opioid use disorder; correct?

14 A. Yes.

15 Q. And, so, the first factor that's listed is a shift in
16 medical practice of prescribing opioids from end-of-life
17 pain and cancer to chronic non-cancer pain, particularly in
18 non-adults [sic]. Do you see that?

19 A. In young adults I think.

20 Q. I'm sorry, young adults.

21 A. Young adults.

22 Q. So do you see that statement?

23 A. I do.

24 Q. And this is a factor that you believe contributed to
25 increases in opioid use disorder in West Virginia?

1 **A.** Yes.

2 **Q.** And next -- the next factor that's referred to is an
3 increased rate of opioid prescription by physicians due to a
4 higher sensitivity to patient's pain. Do you see that?

5 **A.** I do.

6 **Q.** And that's a factor that you believe contributed to
7 increases in opioid use disorder in West Virginia; correct?

8 **A.** Yes.

9 **Q.** Next is the -- a reference to the endorsement of pain
10 as a fifth vital sign by the Joint Commission with a
11 controverted pain metric. Do you see that?

12 **A.** I do.

13 **Q.** And that's a factor that you believe contributed to
14 opioid use disorder in West Virginia; correct?

15 **A.** Yes.

16 **Q.** And then further down it states, "State lobbying by
17 pain advocates for prescription opioid use." Do you see
18 that?

19 **A.** I do. You skipped one. I don't know if you want to go
20 over that one.

21 **Q.** I don't think so, but -- I think that's the next one I
22 wanted to ask you about. And that's a factor that you
23 believe -- the reference I wanted to point you to is state
24 lobbying by pain advocates for prescription opioid use. Do
25 you see that?

1 **A.** I do.

2 **Q.** And that's a factor that you believe contributed to
3 increases in opioid use disorder in West Virginia; correct?

4 **A.** Yes.

5 **Q.** The next one I wanted to ask you about is physician
6 sensitivity to pain exploitation by opioid users. Do you
7 see that?

8 **A.** Yes.

9 **Q.** And that's referring to doctor sensitivity to patients
10 who overstate their medical need for opioids in order to
11 obtain a medication; correct?

12 **A.** That is possible.

13 **Q.** And that's a factor that you believe contributed to
14 increases in opioid use disorder in West Virginia; correct?

15 **A.** Yes.

16 **Q.** The next reference is doctor shopping by patients. Do
17 you see that?

18 **A.** I do.

19 **Q.** And that's a factor that you believe contributed to
20 increases in opioid use disorder in West Virginia?

21 **A.** Yes.

22 **Q.** The next is overprescribing which leaves excess
23 medications available for misuse or redistribution via
24 non-medical sanctioned venues. Do you see that?

25 **A.** Yes.

1 Q. And that's a factor that you believe contributed to
2 increases in opioid use disorder in West Virginia; correct?

3 A. That's right.

4 Q. You don't mention the conduct of wholesale distributors
5 like the defendants anywhere in this article; correct?

6 A. I believe that would be included in the one that you
7 skipped.

8 Q. Which one are you referring to?

9 A. Increased distribution of opioids by the pharmaceutical
10 industry in creation of an opioid-rich environment.

11 Q. And the pharmaceutical industry had secured approval
12 for various opioids; correct?

13 A. They had.

14 Q. And the pharmaceutical industry had secured approval
15 from the FDA to sell opioids based on representations about
16 the risks and benefits of those opioids; correct?

17 A. The opioids were approved by the FDA, yes.

18 Q. And the pharmaceutical industry that had developed
19 those for manufacturers who applied for approval from the
20 FDA for those drugs; correct?

21 A. I'm sorry. Can you say that sentence again? I didn't
22 understand the question.

23 Q. Yes. The, the pharmaceutical manufacturers were the
24 ones who applied to the FDA for approval for drugs based on
25 representations about the risks and benefits of those drugs;

1 correct?

2 **A.** The manufacturers applied to the FDA, yes.

3 **Q.** Let's go to another article that you also wrote. I'm
4 sorry. We already have this one. I've already given you
5 this one, Dr. Keyes. It's the one I've handed you
6 previously, Defendant's Exhibit 2516, "Understanding the
7 Rural-Urban Differences in Non-Medical Prescription Opioid
8 Use and Abuse in the United States."

9 And I think we talked about this. You wrote this
10 article, correct, along with others?

11 **A.** I was a co-author, yes.

12 **Q.** And this article specifically discusses West Virginia;
13 correct?

14 **A.** Yes.

15 **Q.** And this is the article that you -- let me back up.
16 You mentioned in your testimony last week that Mr. Farrell
17 first contacted you after reading an article you had
18 written. This is the article; correct?

19 **A.** That is what he told me.

20 **Q.** I'd like to direct your attention to Page 3 of the
21 article, again using the small numbers on the left.

22 Actually, we've already discussed -- well, I'm going to
23 go to another place in this page.

24 The bottom of the left-hand column, "States with large
25 rural populations such as West Virginia are among the

1 highest prescribers of opioid analgesics."

2 Do you see that?

3 **A.** I do.

4 **Q.** And that's a true statement; correct?

5 **A.** Yes.

6 **Q.** And beginning on Page 3, you identify a number of
7 factors that may explain the high rate of opioid prescribing
8 places like West Virginia; correct?

9 **A.** Well, the article is really about explaining
10 urban-rural differences, not just overall prescribing
11 levels.

12 **Q.** But let me point you to the paragraph I'm thinking of.
13 In the middle column there's a second paragraph that begins
14 "rural populations." That's the paragraph I wanted to ask
15 you about.

16 **A.** Okay.

17 **Q.** And that's a paragraph where you're talking about some
18 of the factors that may lead to higher levels of opioid
19 prescribing in rural populations; correct?

20 **A.** Yes.

21 **Q.** And, so, one point you make in that paragraph is rural
22 populations are on average older and, thus, there may be
23 more chronic pain for which management with opioid
24 analgesics is indicated.

25 Do you see that?

1 **A.** I do.

2 **Q.** And that's a true statement; correct?

3 **A.** Yes, within the context of all the other factors that
4 I'm talking about in the article. But that is one factor
5 that could lead to increases in prescribing.

6 **Q.** In rural areas?

7 **A.** In rural areas.

8 **Q.** Then it goes on to say, "Chronic pain and injury are
9 more common in rural than in urban areas."

10 Do you see that?

11 **A.** I do.

12 **Q.** And that's a true statement; correct?

13 **A.** That was my read of the literature when I was writing
14 this article.

15 **Q.** And you based this article that you wrote in 2014 on
16 the literature you had reviewed; correct?

17 **A.** Yes, at that point.

18 **Q.** And then there's another statement, "Prescription
19 narcotics are often prescribed to maintain a steady work
20 flow in mines and other heavy labor occupations."

21 Do you see that?

22 **A.** That was -- the first part of the sentence specifically
23 referred to Kentucky. But, yes, that's what the sentence
24 says.

25 **Q.** But it's referring to rural areas such as Appalachian

1 Kentucky; right?

2 **A.** Yes.

3 **Q.** And, and I take it that that same observation would
4 apply to rural areas in Appalachian West Virginia; correct?

5 **A.** The specific, you know -- Jennifer Havens, who is a
6 co-author of the article, that's her particular area of
7 interest is Appalachian Kentucky. And, so, I haven't
8 reviewed the literature on whether that generalizes to
9 Appalachian West Virginia.

10 **Q.** So you don't know whether observations about the nature
11 of pain needs in Appalachian Kentucky would be comparable to
12 needs in Appalachian West Virginia? You don't know?

13 **A.** I haven't reviewed that literature, so I wouldn't want
14 to offer an opinion on that.

15 **Q.** Okay. So, so here it's talking about Appalachian
16 Kentucky. By the way, you understand that in Appalachian
17 West Virginia there is a -- there's a heavy work flow in
18 mines and other heavy labor occupations; correct?

19 **A.** I'm generally familiar with the labor industries that
20 are in West Virginia.

21 **Q.** And you understand there's a lot of heavy physical
22 labor expected of the people of West Virginia; correct?

23 **A.** I would say in those particular industries, they are
24 physically laborious.

25 **Q.** And, for instance, mining is an important industry in

1 West Virginia; correct?

2 **A.** I would not offer an opinion on the importance of any
3 one industry. I'm an epidemiologist, so I review the data
4 on what the occupations are.

5 **Q.** Do you have an understanding, though, that, that there
6 is a need for prescription opioids -- well, maybe -- let me
7 back up. Let me ask it a different way.

8 Do you have an understanding that prescription opioids
9 are often prescribed to maintain a steady work flow in mines
10 and other heavy labor occupations? Do you understand that?

11 **A.** I'm sorry. Say that question again.

12 **Q.** Sure. I want to put aside the Appalachian Kentucky
13 point.

14 **A.** Okay.

15 **Q.** I understand what you've said about that.

16 We do agree with each other that West Virginia's also
17 in Appalachia; correct?

18 **A.** Yes.

19 **Q.** And I wanted to ask you about the cause that reads in
20 this article that you wrote, "Prescription narcotics are
21 often prescribed to maintain a steady work flow in mines and
22 other heavy labor occupations."

23 Do you see that?

24 **A.** I do.

25 **Q.** Is that a true statement?

1 **A.** I, I have not reviewed that literature in a lot of
2 detail. I would just refer to the underlying article that
3 is cited there for more context, which I haven't reviewed as
4 of late. So I don't want to offer an opinion about the
5 culture of -- the workplace culture in West Virginia.

6 **Q.** Well, I take it the intention when you wrote the
7 article was to be accurate and to frame, frame accurately
8 what you had determined from the literature at the time you
9 wrote the article; correct?

10 **A.** Of course.

11 **Q.** There's also a next sentence that reads -- no, sorry.
12 I think I asked you already about chronic pain and injury
13 are more common in rural than in urban areas; correct?
14 That's a true statement?

15 **A.** That was based on, on the literature that I reviewed,
16 yes.

17 **Q.** So, so based on these considerations that are listed in
18 this paragraph, you would expect to see higher levels of
19 opioid prescribing in West Virginia than in many other
20 states; correct?

21 **A.** Yes.

22 **Q.** And it's also true that these same factors could lead
23 to different levels of prescribing within an individual
24 state; correct?

25 **A.** I'm sorry. Can you say that again?

1 **Q.** There could be different parts of a state that might
2 have attributes that would be more or less likely to effect
3 prescribing levels within a state; correct?

4 **A.** Well, it would really depend on people's understandings
5 of the risks and benefits. Just because there is opioid
6 prescribing does not necessarily indicate that it's
7 appropriate opioid prescribing.

8 And, so, there is increases in opioid prescribing when
9 you have, for example, older populations. But that doesn't
10 necessarily mean that that opioid prescribing was
11 appropriate.

12 **Q.** I -- maybe I, maybe I didn't ask the right question.

13 **A.** Okay.

14 **Q.** In this paragraph that we've just been going through,
15 you talk about different factors that might lead to higher
16 levels of prescribing in a rural population; correct?

17 **A.** Yes.

18 **Q.** And one factor is that rural populations are on average
19 older and, therefore, there may be more chronic pain for
20 which management by opioid analgesics is indicated. That's
21 one of the factors you identify in this paragraph; right?

22 **A.** Yes.

23 **Q.** And, so, within a particular state, my point is there
24 could be parts of a state that have on average an older
25 population than other parts of the state; correct?

1 **A.** That's right.

2 **Q.** And, so, if you had within a state variations in the
3 population so that one part of the state had an older
4 population, following from this factor you identified there
5 might be higher levels of opioid prescribing anticipated;
6 correct?

7 **A.** It's certainly possible.

8 **Q.** And the same thing could be true for a part of a state
9 that had a heavy -- heavier manual labor component than
10 other parts of the state. That might also lead to a higher
11 level of opioid prescribing in one part of the state than
12 another. Correct?

13 **A.** It's possible, yes.

14 **Q.** So within a state, there could be variations in terms
15 of pain needs based on the nature of the population and the
16 nature of the work?

17 **A.** No, that's not the testimony. I was not speaking of
18 pain needs. I was talking about opioid prescribing.

19 **Q.** Within a state there could be -- I, I was asking you
20 about pain needs. I believe your, your article here is
21 talking about pain needs based on attributes of the
22 population; correct?

23 **A.** There's two factors. One is pain needs and one is
24 opioid prescribing. Those are not synonymous.

25 **Q.** Well, I'm asking about pain needs. You understand that

1 a relatively older population might have higher pain needs;
2 correct?

3 **A.** Yes.

4 **Q.** And a relatively more obese population might have
5 higher pain needs; correct?

6 **A.** It's possible.

7 **Q.** And a, and a population that has a relatively heavier
8 manual labor component to its work might have higher pain
9 needs; correct?

10 **A.** That's possible.

11 **Q.** And, so, within a given state, there might be
12 differences because the population is different for
13 different parts of the state or the work is different for
14 different parts of the state; correct?

15 **A.** That's correct.

16 **Q.** Let me ask you to look at Page 2 of the article,
17 please.

18 On the -- at the bottom of the middle paragraph there's
19 a sentence that reads, "Increased medical use of
20 prescription opioids has resulted in increased access to
21 opioids for non-medical use, either through the non-medical
22 use of legitimately acquired prescriptions or through formal
23 or informal distribution networks."

24 Do you see that?

25 **A.** I do.

1 Q. And that's a true statement; correct?

2 A. That is, that is based in the literature, yes.

3 Q. And, so, the reference here to formal or informal
4 distribution networks, that's a reference to family and
5 friends or drug dealers; correct?

6 A. I would say -- or any kind of social network. I mean,
7 I think we talk in this article about kind of the social
8 networks and differences across urban and rural populations
9 that would interact with opioid supply. So family, friends,
10 people selling drugs, I would say all of those would be
11 included in the informal network.

12 Q. And what would be included in the formal network that
13 you're referring to here? Is that referring to drug
14 dealers?

15 A. That would include drug dealers, yes.

16 Q. Let me ask you at the top of that next column, to the
17 right-hand column, first sentence, --

18 A. I'm sorry. Can I actually qualify that previous
19 statement? Because further on in the article, or in the
20 paragraph I also provide -- I use pill mills and high-volume
21 prescribers and clinics as another example of formal
22 distribution networks.

23 Q. Okay. That's over on the next column; right?

24 A. Yes. I'm sorry. I should have noted that earlier.

25 Q. So that the -- you're saying that your reference to a

1 formal distribution network could include a drug dealer or a
2 pill mill? Is that what you're saying?

3 **A.** That's right.

4 **Q.** There's a statement at the top of the right-hand
5 column, "Studies indicate that the large majority of adults
6 who use opioids non-medically obtain them from friends and
7 relatives or from street-level dealers."

8 Do you see that?

9 **A.** I'm sorry. What page?

10 **Q.** It's at the very top of the right-hand column, the
11 first sentence.

12 **A.** Of Page 2?

13 **Q.** Yes, sorry, yes. Do you see that?

14 **A.** Oh, I do.

15 **Q.** That's a true statement; correct?

16 **A.** Yes. Many people obtain opioids through friends and
17 relatives and street-level dealers.

18 **Q.** And this is occurring after the pills have either been
19 dispensed by a pharmacy or illegally trafficked by dealers;
20 correct?

21 **A.** Again, I think I, I mentioned this before. The data
22 that these are based on and that -- I think the Inciardi
23 study is the one that I would particularly point to relies
24 on people just reporting where they obtain their opioids.
25 And, so, where the family and friends obtain the opioids is

1 not covered in the article.

2 **Q.** But these would be family and friends who have somehow
3 obtained the opioids after they had been dispensed out of a
4 pharmacy; correct?

5 **A.** That's what I'm saying is I don't think that that's
6 covered in the article.

7 **Q.** And you don't have any knowledge of that one way or the
8 other?

9 **A.** I'm relying on the literature. So I'm trying to report
10 faithfully what the literature says. And usually they ask
11 people where they obtain opioids. And if they say family or
12 friends, they don't go to the family or friends and see at
13 what point it arrived in the community.

14 **Q.** There's a statement, the next sentence, "A substantial
15 proportion of overdose deaths and emergency department
16 visits occurs among individuals who have never received a
17 prescription."

18 Do you see that?

19 **A.** Yes.

20 **Q.** And that's a true statement; correct?

21 **A.** Yes, that's what the literature indicates.

22 **Q.** So it's an accurate reflection of what the literature
23 was telling you?

24 **A.** Yes.

25 **Q.** You testified last week about a study done by

1 Christopher Ruhm showing the economic conditions are less
2 than 10 percent responsible for the opioid crisis; correct?

3 **A.** That's right.

4 **Q.** And Christopher Ruhm did an econometrics study where he
5 was looking at economic factors that may interrelate with
6 prescription opioid abuse; correct?

7 **A.** I believe it was prescription opioid distribution.

8 **Q.** Are you aware that Ruhm only considered the impact of
9 economic conditions and not any of these other factors that
10 you've discussed in this paper that we're looking at right
11 now?

12 **A.** I, I believe that the Ruhm article also discusses other
13 factors, including the illicit drug supply.

14 **Q.** But you're aware that the way Ruhm measured factors, he
15 was trying to explain what might lead to opioid use
16 variation in different parts of the country; correct?

17 **A.** I'm sorry. Say that again.

18 **Q.** Ruhm was trying to explain factors that might lead to
19 variations in opioid use in different parts of the country;
20 correct?

21 **A.** If you have the article, I'd like to see it.

22 **Q.** I do.

23 MR. HESTER: May I approach, Your Honor?

24 BY MR. HESTER:

25 **Q.** Here it is.

1 **A.** So I'm looking at the key --

2 **Q.** Let me --

3 **A.** I didn't catch the question.

4 **Q.** Let me just set the table first.

5 Dr. Keyes, I've handed you a document marked as
6 Defendants' West Virginia Exhibit 2344 headed on the first
7 page, "Deaths of Despair or Drug Problems?" Christopher
8 Ruhm.

9 Is this the Ruhm paper that you were referring to in
10 your testimony last week?

11 **A.** Yes.

12 **Q.** And, and the Ruhm paper was undertaking to evaluate
13 factors that might cause increased drug overdose deaths;
14 correct? And I, I can point you -- it's not a trick
15 question. It's a thick paper. But I can point you to -- if
16 you look at Page 7 using the small numbers on the left.

17 **A.** Okay.

18 **Q.** And in the middle of the paragraph Ruhm has a
19 reference, "Third, in the preferred specifications changes
20 in economic conditions explain less than one-tenth of the
21 observed increase in drug deaths."

22 Do you see that?

23 **A.** Yes.

24 **Q.** And that's my point is that Ruhm was trying to look at
25 changes in economic conditions that might explain drug

1 deaths; is that correct?

2 **A.** That's one finding of the article. There are four.

3 But that is one finding of the article.

4 **Q.** And he based his equations -- there's equations all
5 through this article; correct?

6 **A.** There are.

7 **Q.** And he based his analysis on measurements of economic
8 conditions; correct?

9 **A.** In addition to the factors that he controlled for,
10 which were the ones that you mentioned in the previous
11 article.

12 He controlled for age, morality. He had a nine-level
13 variable controlling for population density, race, college
14 education, gender, Hispanic ethnicity; a seven-category
15 variable for age which would account for your -- what you
16 mentioned earlier about the age differences across
17 populations if one county had more older folks than another
18 county.

19 **Q.** But --

20 **A.** He also looked at the proportion of households headed
21 by females. Sorry. Do you want me to keep reading?

22 **Q.** No. I was just going to say -- to take a simple,
23 concrete example, Ruhm did not measure, for instance,
24 differences in the nature of the manual labor in different
25 parts of the country?

1 **A.** I believe there are labor codes in the paper. I know
2 Ruhm has done quite a few papers on labor markets. So I
3 haven't read this article in detail --

4 **Q.** Okay.

5 **A.** -- before here, but I -- Ruhm has done pretty extensive
6 evaluations of labor markets in rural counties and how that
7 contributes to drug overdose.

8 **Q.** Did you know -- I'm correct, am I, that Ruhm did not
9 have measurements of pain needs in different parts of the
10 country in his, in his equations; correct?

11 **A.** Well, I would say that there are proxies for that based
12 on what you mentioned before such as age and underlying
13 medical conditions that would be indicated by these
14 different demographic and other clinical categories that
15 were included in the control variables.

16 **Q.** But not, for instance, nature of the work?

17 **A.** Again, I think that to the extent that labor codes were
18 included in this analysis, that would be accounted for.

19 THE COURT: We're going to need to take a break
20 when you get to a stopping place.

21 MR. HESTER: All right, Your Honor. This is a
22 good place for me.

23 THE COURT: Is this a good place?

24 MR. HESTER: Yes. Thank you.

25 THE COURT: Okay. Let's be in recess for about 10

1 minutes.

2 (Recess taken at 10:24 a.m.)

3 THE COURT: All right, Mr. Hester.

4 MR. HESTER: Thank you, Your Honor.

5 BY MR. HESTER:

6 **Q.** Dr. Keyes, I wanted to be clear on one point, that you
7 have not identified any sources of diversion in relation to
8 shipments between distributors and pharmacies; is that
9 correct?

10 **A.** I have not covered that in my report.

11 **Q.** And you've not identified any such diversion between
12 the time that a distributor has the pills and the time it
13 delivers to a pharmacy, correct?

14 **A.** I'm aware that that occurs. I mean, there are thefts
15 that occur on -- that that happens, so that would be a
16 source of diversion.

17 **Q.** But you've not identified any such sources, correct?

18 **A.** Other than that it occurs and it's included in my
19 definition of diversion.

20 **Q.** Could we pull up the deposition from this litigation,
21 please, Page 113? Page 113, Line 13. Dr. Keyes, I started
22 off the question and said, "Right, but I wanted -- just to
23 be clear", and I think so we're talking the same language
24 here and then I asked you this question. "I want to be
25 clear that you're not identifying any sources of diversion

1 in relation to shipments between distributors and
2 pharmacies. You haven't identified any such evidence?" And
3 your answer was, "Right." Was that correct when you -- was
4 that a correct answer when you gave it?

5 **A.** I don't think so. I mean, I know in the Inciardi
6 article, in the introduction, it does specifically talk
7 about theft. You know, so I think if I were answering the
8 question today, which I am, I would point to -- there have a
9 couple sources in the Inciardi 2008 introduction about --
10 about that type of diversion. So, I think that I would -- I
11 would qualify that answer today.

12 **Q.** My question is, when you gave that answer, were you
13 under oath?

14 **A.** Yes.

15 **Q.** And when you gave that answer, did you mean to be
16 answering correctly and truthfully?

17 **A.** I meant to be answering correctly and truthfully.

18 **Q.** And that's the answer you gave when I asked you,
19 "You're not identifying any sources of diversion in relation
20 to shipments between distributors and pharmacies? You
21 haven't identified any such evidence?" And your answer was,
22 "Right." Is that correct?

23 **A.** That was my answer.

24 **Q.** And that was meant to be truthful when you gave it,
25 correct?

1 **A.** I hadn't remembered the Inciardi article and the
2 references that were in that introduction.

3 **Q.** Dr. Keyes, was that meant to be truthful when you gave
4 the answer?

5 **A.** It was meant to be truthful.

6 **Q.** Let me ask you, Dr. Keyes, a couple of preliminary
7 points around doctor prescribing activity. Doctors decide
8 on the dosage strength to include in a given prescription,
9 correct?

10 **A.** Can you say the question again?

11 **Q.** Sure. Doctors decide on the dosage strength to include
12 in a particular prescription, correct?

13 **A.** Yes.

14 **Q.** And also, doctors decide how many pills to include in a
15 given prescription for opioids, correct?

16 **A.** That's right.

17 **Q.** In other words, a doctor makes the judgment whether to
18 include a 10-day supply, a 30-day supply, or some other
19 duration for the prescription of the opioid, correct?

20 **A.** A doctor makes the decision about that, yes.

21 **Q.** And your view is that the overwhelming majority of
22 doctors prescribe opioids to their patients in good faith,
23 correct?

24 **A.** I don't know what proportion prescribe in good faith
25 but I would -- my opinion would be that it would be a

1 majority who make prescriptions based on the information
2 that they have.

3 **Q.** Well, let me ask it again just to be clear. Your view
4 is that the overwhelming majority of doctors prescribe
5 opioids to their patients in good faith, correct?

6 **A.** Yes. I -- I think that that is true. They base it on
7 the decision -- the information that they have.

8 **Q.** And starting in the late 1990s up through around 2010,
9 doctors increased their prescribing of opioids, correct?

10 **A.** Yes.

11 **Q.** And you wrote in your report at Page 23, if you want to
12 look at it, but I'll quote it to you. I think it will sound
13 familiar to you. "Pervasive over-prescribing resulted in
14 unused prescription opioid medicines diverted for monetary
15 value, bartered or for no cost among family and individuals
16 in a shared social network." Do you want me to point you to
17 that passage?

18 **A.** Yes, if you don't mind. I'm on Page 23.

19 **Q.** Yes. So, it's at Page 23 of your report. Let me see
20 if I can find it. It's in the middle of the page, Dr.
21 Keyes. There's a -- there's a bolded sentence.

22 **A.** I -- yes. It's at the top of my Page 23. Maybe we
23 have different versions.

24 **Q.** Oh, yes. Yes. You're right. Absolutely. At the top,
25 the sentence that -- and there's a sentence that's bolded

1 and it says, "Pervasive over-prescribing resulted in unused
2 prescribed opioid medications diverted for monetary value,
3 bartered, or for no cost among family and individuals in a
4 shared social network." Do you see that?

5 **A.** I do.

6 **Q.** And that's a true statement, correct?

7 **A.** That's my read of the literature.

8 **Q.** And the reference there to diverted for money, barter,
9 or no cost, that's diversion after the pills have either
10 been prescribed or illegally trafficked into the community,
11 correct?

12 **A.** With regard to over-prescribing, that is specifically
13 focused on prescribing behavior. There's another section,
14 oversupply.

15 **Q.** So, your point is that there was a pervasive
16 over-prescribing that led to unused pills and then they went
17 from the people who were prescribed those pills to others,
18 either through barter, through money, or through giving them
19 away, correct?

20 **A.** That's one source of the oversupply.

21 **Q.** And you also state in just a few sentences down in this
22 same paragraph of your report that, "Available estimates
23 indicate that 90 percent of patients prescribed opioids
24 after surgery have unused medication, most of which is not
25 disposed of or stored safely." Do you see that?

1 **A.** I do.

2 **Q.** And that's a true statement, correct?

3 **A.** Yes.

4 **Q.** And that's based on your --

5 **A.** In the literature that I read.

6 **Q.** Yeah. And so, when you -- when you say in the
7 literature you've read, you're purporting to give an
8 accurate summary of the literature when you state this?

9 **A.** I'm purporting to, yes.

10 **Q.** And that's your best effort?

11 **A.** Yes. I always update, you know, my opinions and
12 information with new -- new information as I'm gathering it.
13 So, I just want to be clear that I'm basing my statement on
14 the literature as I've read it.

15 **Q.** But when you wrote your report you meant to be
16 accurately reflecting the literature as you know it at the
17 time?

18 **A.** I certainly did.

19 **Q.** And the point you're making here in this sentence about
20 available estimates indicate that 90 percent of patients are
21 prescribed opioids have unused medication after surgery, the
22 point you're making there is that even though there might be
23 an underlying legitimate need for the prescription opioid,
24 the doctor prescribes too many pills to meet the need,
25 correct?

1 **A.** It's not referring to the legitimacy of the need. It
2 is referring to the -- the -- that there were too many pills
3 prescribed but I'm not -- that these studies did not
4 ascertain the legitimacy of the prescription itself, only
5 that there were unused medications. So, it could also be
6 that the prescription wasn't needed and that there were
7 unused medications.

8 **Q.** You're aware that many times prescription opioids are
9 prescribed for people after surgery to deal with acute pain,
10 correct?

11 **A.** It depends on the type of surgery. The amount of
12 prescription opioids that are prescribed depends on what
13 surgery we're talking about. There's many different kinds
14 of surgery.

15 **Q.** My question was narrower and probably simpler than
16 that, which is you are aware that prescription opioids are
17 often prescribed for treatment of acute pain after surgery,
18 correct?

19 **A.** Again, I think that that's too broad of a statement.

20 **Q.** You're not aware of that?

21 **A.** I am aware that opioids can be prescribed after some
22 surgeries.

23 **Q.** And so, the point is, there may be a surgery where
24 prescription opioids are prescribed to deal with the pain
25 after surgery, but in your review of the literature, you

1 determine that in 90 percent of those cases there were
2 unused medicines left after the person used them for
3 treating pain?

4 **A.** That's right.

5 **Q.** And that's a judgment being made by the doctor about
6 how many pills to include in that prescription for the
7 surgery, treatment of the pain following surgery, correct?

8 **A.** That's right.

9 **Q.** And so, this could happen quite often, correct, that
10 there might a circumstance where a prescription is written
11 and a doctor writes too many pills for that given
12 prescription, correct?

13 **A.** Yes.

14 **Q.** And the physician, in the good faith exercise of
15 judgment, decides to prescribe an opioid to meet a
16 particular need for a particular kind of pain, correct?

17 **A.** Can you state the question again?

18 **Q.** Yes. So, you could have a circumstance, I take it
19 there's many circumstances where a doctor could make a
20 legitimate good faith decision to prescribe opioids to deal
21 with a particular kind of pain, correct?

22 **A.** As I've said before, the doctor is making a
23 determination based on their understanding of the risks and
24 benefits of a particular opioid prescribing, which itself
25 has changed over time. You know, certainly, the

1 recommendations for prescribing have changed quite a lot
2 over the last ten years. And so, I'm not arguing that there
3 are not doctors that are acting in, quote-unquote, "good
4 faith" to write, quote-unquote "legitimate prescriptions",
5 but that that -- these studies are not purporting to report
6 on the efficacy or legitimacy of a particular prescription.
7 That's a separate evidence base.

8 **Q.** But going back to what we established a few minutes
9 ago, your view is that the overwhelming majority of doctors
10 prescribe opioids in good faith, correct?

11 **A.** Yes. I think many doctors are doing their best.

12 **Q.** The overwhelming majority, correct?

13 **A.** Certainly, yes, the majority.

14 **Q.** The overwhelming majority, correct?

15 **A.** Yes.

16 **Q.** And then the doctor acting in good faith to prescribe
17 the opioid may provide for more pills in that prescription
18 than are needed to meet the need for which the pills are
19 being prescribed, correct?

20 **A.** That can happen, yes.

21 **Q.** And in that case, even though the doctor has decided
22 that the medical need is legitimate, the doctor has
23 prescribed more pills than are needed to meet the need,
24 correct?

25 **A.** The doctor has made a determination of a medical need

1 and has prescribed too many pills in that circumstance that
2 you're -- this hypothetical that you're offering.

3 **Q.** And so, at Page 23 of your report, again, the same
4 page, the same paragraph, actually, you state that, among
5 non-medical opioid users interviewed about where they obtain
6 their opioids, 50.5 percent report from a friend or
7 relative.

8 Do you see that? It's almost exactly in the middle of
9 that paragraph. It's the sentence that begins data from the
10 National Survey on Drug Use and Health.

11 **A.** Yes. 50.5 percent receive -- in that survey received
12 prescription opioids from a friend or family.

13 **Q.** So, let's just be clear on what that is. It's a survey
14 from the National -- from the organization called NSDUH,
15 which is the National Survey on Drug Use and Health,
16 correct?

17 **A.** That's the -- the name of the survey is NSDUH.

18 **Q.** And that's a government survey that's run --

19 **A.** Yes.

20 **Q.** -- periodically?

21 **A.** Annually.

22 **Q.** And in that survey the report is that 50.5 percent of
23 non-medical users of opioids stated that they obtained the
24 opioids from a friend or a relative, correct?

25 **A.** Among the respondents in that survey, yes.

1 **Q.** And your analysis in the report of this passage was
2 that quite a bit of that was the result of unused
3 medications after a particular prescription, correct?

4 **A.** My analysis included unused prescriptions. The
5 previous sentence uses that statistic in citing evidence for
6 the proposition that the expansion of opioid sales and
7 distribution served as a catalyst for the overall
8 availability and one consequence would be unused medication.

9 **Q.** So, you would have unused medication that would be a
10 ready source of diversion to others from family and friends,
11 correct?

12 **A.** That's one pathway, yes.

13 **Q.** You also state just a -- I think in the next sentence
14 that the NSDUH data showed -- oh, sorry. Let me go down two
15 sentences further. There's another sentence that reads,
16 "Data from the NSDUH show that 57 percent of non-medical
17 opioid users in 2007 obtained opioid -- opioids from family
18 or relative for free with another 9 percent reporting that a
19 friend or a relative for purchase was also a source of the
20 opioids."

21 Do you see that?

22 **A.** I do.

23 **Q.** So, and that's a true statement, correct?

24 **A.** That is. Well, sorry. It's like -- it's based on my
25 review of the literature or I guess my reading of those

1 statistics from the NSDUH.

2 **Q.** Right. So, you're accurately reporting what NSDUH
3 reported, correct?

4 **A.** Yes.

5 **Q.** And the point is, so that would add up to 66 percent of
6 non-medical users obtaining pills from friends or family in
7 2007, correct?

8 **A.** Not exactly. That -- the survey -- it was not a
9 mutually exclusive category. People could report all of the
10 sources they obtained opioids from, including a doctor,
11 friends and family, a drug dealer; and then friends and
12 family for free, friends and family for money.

13 So, it's not -- can't add them up. You know, there's
14 going to be overlap. Some people got them for free from
15 family or friends and then, later on, they bought them from
16 a friend. You know, so --

17 **Q.** I see. I see what you're saying. So, but the point
18 is, the survey reflected, again, that more than half of the
19 people who were non-medical users, in other words, people
20 who are using opioids without a prescription, more than half
21 reported they had obtained the opioids from a friend or
22 relative for free, correct?

23 **A.** That's true, but that's not the -- that might not be
24 the only source. But that is a source. It's a -- it's a
25 very common source for opioids.

1 Q. So, fair enough. So, somebody who is a non-medical
2 opioid user might get some for free from family, but then
3 might also go out on the street and buy some more, correct?

4 A. Well, I think more germane to the discussion, most
5 non-medical users also obtain opioids medically. So,
6 there's a large overlap between those two. They're not
7 distinct. You don't have one group of legitimate opioid
8 users and one group of non-medical users. There is a lot of
9 overlap between those two groups.

10 Q. But you would have -- you could have a circumstance
11 where somebody is a non-medical user, they might have a
12 prescription for some, but then they obtain other pills from
13 family or friends for free, correct?

14 A. That's right.

15 Q. Or you could have a circumstance where somebody has a
16 prescription for opioids, but they also go out and buy
17 opioids on the street, correct?

18 A. That is a -- that is a scenario that occurs.

19 Q. And they're non-medical users, so they -- by
20 definition, they are using opioids for some non-medical
21 purpose, correct?

22 A. That's right.

23 Q. And your view is that the high volume of opioid
24 prescriptions that doctors were writing became the
25 foundation for the overall expansion of the opioid supply,

1 correct?

2 **A.** Can you say that sentence again?

3 **Q.** Yes. Your view is that the high volume of opioid
4 prescriptions that doctors were writing became the
5 foundation for the overall expansion of the opioid supply,
6 correct?

7 **A.** That is a major source of the foundation, yes.

8 **Q.** And, in your view, it is -- it was a principal
9 foundation of the expansion of the supply of opioids,
10 correct, the prescribing by doctors?

11 **A.** I think it's a major foundation of the increases in
12 prescribing and, you know, what we saw subsequently with the
13 heroin epidemic.

14 **Q.** And your view is that the high volume of opioid
15 prescriptions also became the foundation for the overall
16 expansion and opioid-related harm, correct?

17 **A.** The high volume of prescribing was a foundational
18 source of the epidemic that followed, including our current
19 fentanyl epidemic.

20 **Q.** And it was the foundation for the overall expansion and
21 opioid-related harm, correct?

22 **A.** Yes. It was a principal source. I would say there's
23 other sources. You know, it's a -- in these epidemics where
24 you have a lot of different underlying and interacting
25 factors, certainly, the pervasive over-prescribing was one

1 of the foundational ones.

2 **Q.** And one of the foundational ones in particular for the
3 expansion of opioid-related harm was the level of
4 prescribing by doctors, correct?

5 **A.** The level of prescribing by doctors certainly
6 contributed to the availability of opioids in the community.
7 So, I would say that that is a true statement, but it is not
8 exclusive of other sources of prescription opioids, as I've
9 outlined and we've discussed.

10 **Q.** But let me -- let me be clear on it. Just let me ask
11 it one more time. You agree that the high volume of opioid
12 prescriptions became the foundation for the overall
13 expansion in the opioid supply and opioid-related harm,
14 correct?

15 **A.** Yes. I believe I've written that before, but in
16 context, I would just say it's a foundation.

17 **Q.** Yes. So, your answer is yes to my question?

18 **A.** Yes.

19 **Q.** And then, your view is that the opioid crisis would not
20 have occurred if prescribing opioids had not become standard
21 practice in managing acute and chronic pain, correct?

22 **A.** That's right.

23 **Q.** Distributors did not ship more pills than doctors
24 prescribed, correct?

25 **A.** I haven't evaluated the distributor shipments, so I

1 wouldn't want to comment on them. I don't have an opinion
2 on that.

3 **Q.** You're aware, I take it, that no matter how many
4 opioids a distributor ships to a given pharmacy, if there's
5 not a prescription from a doctor, those opioids stay on the
6 pharmacy shelf and never reach the community, correct?

7 **A.** My understanding generally is that that's how it's
8 supposed to work. I don't know exactly how it worked in
9 every circumstance here.

10 **Q.** Well, let me ask it again just to make clear. No
11 matter how many opioids a distributor ships to a given
12 pharmacy, if there's not a prescription from a doctor, those
13 opioids are supposed to stay in the pharmacy and not go out
14 to the public, correct?

15 **A.** They certainly are supposed to.

16 **Q.** And so, you -- the answer is yes?

17 **A.** Yes.

18 **Q.** You published an article in 2013 that said, "The data
19 are robust in demonstrating that rates of overdoses are
20 proportional to the rates of prescribing", correct?

21 **A.** Which article is this?

22 **Q.** I'm not sure if I have that article right handy. Do
23 you remember publishing such an article that said that, "The
24 data are robust in demonstrating that rates of overdoses are
25 proportional to the rates of prescribing"?

1 **A.** I certainly agree with the statement. I would just
2 prefer to see the article if I'm going to be quoted to make
3 sure I'm --

4 **Q.** Okay. So, you agree with this statement that rates of
5 overdoses are proportional to the rates of prescribing of
6 opioids?

7 **A.** Yes.

8 **Q.** Dr. Keyes, I think we've talked about this before, but
9 you do understand that drug trafficking organizations and
10 drug dealers illegally supply prescription opioids in
11 Huntington and Cabell County, correct?

12 **A.** You said illegally?

13 **Q.** Yes.

14 **A.** Yes.

15 **Q.** And those illegal acts expand the total supply of
16 prescription opioids in Cabell County and Huntington,
17 correct?

18 **A.** Say -- say the question again.

19 **Q.** Yes. Those illegal acts of drug trafficking into
20 Cabell County and Huntington expand the total supply of
21 prescription opioids in the community, correct?

22 **A.** Yeah. There's literature on this in my report. I
23 mean, certainly, it's a minority. The analyses that have
24 been done suggest that it's a minority of all of the
25 opioid-related harm in the Cabell-Huntington community.

1 But, certainly, there is illegal trafficking that occurs and
2 that does contribute to harm.

3 **Q.** And the illegal trafficking also expands to the total
4 supply of prescription opioids, correct?

5 **A.** To -- yes. There's a -- I would say it's minority of
6 the total supply, certainly, but it certainly does
7 contribute to it.

8 **Q.** Contribute to the supply of opioids, correct?

9 **A.** It contributes to the supply of opioids, yes.

10 **Q.** And so, drug trafficking also contributed to the
11 opioid-related harms that you identify, correct?

12 **A.** Yes.

13 **Q.** And we talked before about the fact that drug dealers
14 make and sell counterfeit opioid pills, correct?

15 **A.** They can.

16 **Q.** And that includes counterfeit opioid pills that are
17 adulterated with fentanyl, correct?

18 **A.** That -- that has occurred, yes.

19 **Q.** And people have overdosed and died from those
20 counterfeit opioid pills, correct?

21 **A.** The multiple cause of death filed in the CDC doesn't
22 differentiate illicit from licit prescription opioids. So,
23 I'm certainly -- it's certainly likely that someone has
24 overdosed from a prescription opioid, but the data that I
25 rely on in the report does not distinguish those two.

1 **Q.** Well, let me ask it again to be clear. You're aware
2 that people have overdosed and died from counterfeit opioid
3 pills, correct?

4 **A.** I'm sure it has occurred, but I have not reviewed data
5 on specific counterfeit opioid overdoses.

6 MR. HESTER: Could we cull up the deposition,
7 please, from this case, Page 324?

8 BY MR. HESTER:

9 **Q.** Dr. Keyes, let me point you to Line 3. My question
10 was, "And are you aware that people have overdosed and died
11 from pills like that?" And if you need me to go back and
12 show you the context, I can, but this is discussing
13 counterfeit pills. That was my question.

14 Do you see that?

15 **A.** Yes.

16 **Q.** And your answer was, "Yes, I have. I'm aware that that
17 occurs."

18 Do you see that?

19 **A.** I do.

20 **Q.** And was your answer correct when you gave it?

21 **A.** Yes. That's -- I think it's consistent with what I've
22 just reported.

23 **Q.** And so, these counterfeit pills also expanded the
24 supply of opioids in Huntington and Cabell County, correct?

25 **A.** Yes. I think it's a minority contribution to the

1 supply, a small minority.

2 **Q.** But you don't know the percentage of prescription
3 opioids in Huntington and Cabell County that -- that were
4 counterfeit, do you?

5 **A.** Well, we can estimate it somewhat from the data, which
6 I have tried to do in the report and which I believe is
7 reflected in that testimony, as well, that based on what we
8 know about what people report in terms of where they obtain
9 opioids, I would say it's maybe 10 percent, I think
10 somewhere around there.

11 **Q.** Would be counterfeit opioids?

12 **A.** Well, would be illicit opioids.

13 **Q.** Which would include counterfeits?

14 **A.** Which would include counterfeit.

15 **Q.** But that could also include counterfeits that are laced
16 with fentanyl and might be more lethal than a conventional
17 prescription opioid, correct?

18 **A.** Well, the lethality of the opioid is really determined
19 by the dose. So, the probability of an overdose is
20 dependent on the dose of the opioids that you take. And so,
21 a conventional opioid and an opioid laced with fentanyl, for
22 example, if they had a different dose, then that would
23 change the overdose risk.

24 **Q.** Do you have any understanding whether a counterfeit
25 pill laced with fentanyl is more or less risky than a

1 conventional prescription opioid pill?

2 **A.** Well, I think that's comparing apples and oranges. So,
3 if we're comparing two doses, you know, a conventional
4 prescription opioid pill compared to a counterfeit pill that
5 has opioid -- has fentanyl in it, if the fentanyl pill has a
6 larger dose, which it probably does if it has fentanyl, then
7 it would be riskier. But I don't think you could compare
8 the pills directly unless you're comparing -- unless they
9 have equivalent doses.

10 **Q.** Let me flip to a slightly different topic and it builds
11 on something you said a few minutes ago. You're aware that
12 there are different dosages for opioid medications, correct?

13 **A.** Yes.

14 **Q.** And so, there may be different judgments made by a
15 doctor in prescribing opioids about what dose to use for a
16 particular patient, correct?

17 **A.** Yes. A doctor would make -- two doctors might make a
18 different decision about the dosage.

19 **Q.** And the doctors are the ones who make the judgment
20 about what dose should be prescribed for a particular
21 patient and a particular need, correct?

22 **A.** Yes, based on the information that's been given to
23 them.

24 **Q.** And opioid medications can also be prescribed for
25 different durations, correct?

1 **A.** That's right.

2 **Q.** For instance, a prescription to treat acute pain with
3 opioids might be for a different duration than a
4 prescription to treat some longer-term pain, correct?

5 **A.** I wouldn't make a blanket statement because there's
6 been plenty of acute conditions that people have gotten
7 quite a long duration of opioid pills for. So, it would
8 really depend on the condition, the doctor, and what
9 condition we're comparing it to.

10 **Q.** But the doctor will make the judgment both about the
11 dose and the duration for a particular prescription or for a
12 particular regimen of treatment, correct?

13 **A.** A doctor would make the decision based on the
14 information available to him or her.

15 **Q.** And you are aware that opioids are used to treat
16 different kinds of pain beyond chronic pain, correct?

17 **A.** Am I -- say that -- that question again, please.

18 **Q.** You are aware that opioids are used to treat different
19 kinds of pain beyond chronic pain?

20 **A.** I'm aware that they are used.

21 **Q.** To treat different kinds of pain beyond chronic pain?

22 **A.** Yes.

23 **Q.** And not every patient treated with opioids uses them
24 chronically or for a long time, correct?

25 **A.** That's right.

1 **Q.** And so, some patients might use prescription opioids
2 only for a few days or for quite a short period of time,
3 correct?

4 **A.** It's certainly possible that there's -- well, the
5 literature shows that there are people who use for a short
6 duration and people who use for a long duration. So, yes,
7 there are people who use opioids for a short duration.

8 **Q.** You testified on Friday about an article by Edlund and
9 colleagues that provides information on the incidence of OUD
10 based on different levels of dose and duration, right?

11 **A.** Yes.

12 **Q.** And when you talk about incidence of OUD, that means
13 new OUD; in other words, how many people develop OUD after
14 they receive an opioid prescription. That's -- that's what
15 you mean by incidence, right?

16 **A.** OUD is typically episodic. And so, I believe in the
17 Edlund article they were looking at new episodes of Opioid
18 Use Disorder.

19 **Q.** So, in other words, it would be Opioid Use Disorder
20 that arises in some percentage of people after they're
21 exposed to prescription opioids?

22 **A.** That's right.

23 **Q.** So, let's take a look at that Edlund study, please.

24 MR. HESTER: May I approach, Your Honor?

25 BY MR. HESTER:

1 **Q.** Dr. Keyes, we've handed you what's been marked as
2 DEF-WV-2307. On the first page it's headed The Role of
3 Opioid Prescription in Incident Opioid Abuse and Dependence
4 Among Individuals With Chronic Non-Cancer Pain.

5 Do you see that?

6 **A.** And the second part is The Role of Opioid Prescription.

7 **Q.** Right. And this is the Edlund article that you were
8 referring to in your testimony last week, correct?

9 **A.** Correct.

10 **Q.** And you consider this article to be accurate, correct?

11 **A.** Based on my reading of it, I have judged it to be of --
12 scientifically meritorious, I would say.

13 **Q.** And you testified last week that it's relied on by
14 epidemiologists in your field when performing research on
15 opioid use and Opioid Use Disorder, correct?

16 **A.** Yes.

17 **Q.** And you also testified that this article is respected
18 and not subject to any underlying questions of veracity,
19 correct?

20 **A.** Not that I'm aware of.

21 MR. HESTER: Your Honor, I would move this
22 document into evidence.

23 THE COURT: Any objection?

24 MR. FARRELL: Judge, I'm not quite sure it's
25 proper to admit medical literature into the record as

1 evidence. I'm not necessarily opposed to it, but you'll
2 recall that the defendants objected to me even showing you
3 the medical literature, let alone entering it into the
4 record. So, I'm a little befuddled as to the purpose of and
5 the propriety of entering medical literature into the record
6 at this stage.

7 MR. HESTER: Well, Your Honor, the witness
8 testified last week that this is a respected article, that
9 there are no issues of underlying veracity or accuracy to
10 her understanding with this article, that it's relied on by
11 epidemiologists in the field. It was highlighted in the
12 testimony presented on Friday to the Court.

13 It seems to us that, given the witness's testimony, it
14 satisfies the residual hearsay exception because we've --
15 the record now demonstrates sufficient indicia of
16 trustworthiness as to this document.

17 We also think it would be helpful to the Court because
18 it has been highlighted and discussed at some length and it
19 feels, to us, helpful in the sense of the Court being able
20 to rely on the document and to -- and to have it available
21 in the record.

22 THE COURT: Mr. Farrell?

23 MR. FARRELL: Well, Judge, you're the trier of
24 fact. And so, I think that the purpose of the hearsay rules
25 is in general to keep out of the record items that are not

1 reliable or trustworthy and I am fully confident that Your
2 Honor has the ability to apply appropriate weight but,
3 again, this is not a non-traditional procedural aspect of
4 the case.

5 Of course, I'm accustomed to jury trials and not bench
6 trials. So, I'll leave it to Your Honor's discretion
7 whether you think it will assist you and, if it does, I have
8 a host of other medical journals that I would like to
9 supplement when it's my turn to re-direct.

10 MR. HESTER: Well, Your Honor, I'm not -- I'm not
11 purporting to offer some sort of deal to Mr. Farrell. It
12 just seemed to me that the witness gave quite a bit of
13 specific testimony on this specific document that makes it
14 different from the norm of any piece out of the literature
15 because she specifically spoke to the reliability and
16 veracity of this particular document.

17 THE COURT: Well, I don't think you've got this
18 within Rule 807, Mr. Hester, so if there's an objection to
19 it, Mr. Farrell, I'll sustain the objection.

20 Is there an objection to it?

21 MR. FARRELL: Yes. Yes.

22 THE COURT: Well, I'm not going to admit it but,
23 Mr. Hester, it's fair game for you to question her about it.

24 MR. HESTER: Thank you, Your Honor. I'll do it
25 that way. That's totally fine.

1 THE COURT: Okay.

2 BY MR. HESTER:

3 Q. Dr. Keyes, I know you're familiar with this, but I
4 think we need to put in some pieces into the record just to
5 clarify the nature of this study. So, the study focused on
6 adults 18 and over with a new chronic non-cancer pain
7 episode and no opioid use or OUD in the prior six months; is
8 that correct?

9 A. That's right.

10 Q. And the sample included 568,640 individuals in total,
11 correct?

12 A. Yes.

13 Q. And that's a relatively large sample size for a study
14 like this, correct?

15 A. For a study like this that is based on medical records,
16 I would say it's fairly standard, but it is, you know, a
17 large sample size.

18 Q. And the study was -- I can point you to Page 4, but you
19 may know this one out of your head. This study was designed
20 to measure the incidence of OUD following exposure to
21 different levels of prescribed opioids, correct?

22 A. Yes.

23 Q. And it reports levels of incidence OUD; in other words,
24 new OUD for both acute and chronic pain treatment, correct?

25 A. Yes.

1 Q. And here, when the article refers to acute, it refers
2 to the length of the opioid therapy, correct?

3 A. That's right.

4 Q. So, it's not -- when it uses the term "acute", it's not
5 referring to the type of pain, but the duration of the
6 treatment, correct?

7 A. Yes.

8 Q. And it defined acute as treatment for less than 90 days
9 with prescription opioids, correct?

10 A. It was inclusive of 90 days. So, 90 days or less.

11 Q. Got it. We're with you. We're with each other. So,
12 90 days or less would be defined in this study as acute
13 treatment, correct?

14 A. That's right.

15 Q. And so, chronic treatment was -- 90 days or more was
16 considered chronic in this study, correct?

17 A. More than 90.

18 Q. So, more than --

19 A. So, 91 or more.

20 Q. Thank you. Thank you. So -- so, let's look at the
21 results and we can see the results at Page 3 of the document
22 discussing the results and the first full paragraph in the
23 right-hand column. Let me confirm, Dr. Keyes, that for
24 acute or short-term pain treatment; in other words, 90 days
25 or less, the rates of new OUD were .12 percent for patients

1 who were treated with a low dose, correct?

2 **A.** I'm sorry. Which page are you on? I just want to make
3 sure that I --

4 **Q.** I was looking at Page 3.

5 **A.** I'm sorry. I was looking at Page 4.

6 **Q.** In the right-hand column and the third sentence. This
7 refers to the unadjusted rates of post-index OUD diagnosis.
8 Do you see that?

9 **A.** Yes.

10 **Q.** And so, when we talk about post-index OUD diagnosis
11 that's referring to the -- to the percentage of people who
12 were treated with a given dose duration of prescription
13 opioids and it's referring to the percentage of people who
14 developed OUD, correct?

15 **A.** That's right.

16 **Q.** And so, the results reflect that there was a -- an
17 incidence of .12 percent for patients who were treated with
18 a low dose for less than 90 days, correct?

19 **A.** That's right.

20 **Q.** And .12 percent, as well, for patients treated with a
21 medium dose for 90 days or less, correct?

22 **A.** .12, yes.

23 **Q.** And the same is true for patients treated with a high
24 dose for 90 days or less, that the incidence level of OUD
25 was .12 percent, right?

1 **A.** That's right.

2 **Q.** And so, turning that around, that -- that means that
3 over 99.8 percent of patients who were treated with
4 prescription opioids, no matter what the dose, did not
5 develop OUD if they were treated for less than 90 days,
6 correct?

7 **A.** That's right.

8 **Q.** Now, let's look at the other side of the coin, chronic
9 or longer term treatment. So, more than 90 days. And the
10 rates of OUD there were .7 percent for patients who were
11 treated with a low dose for more than 90 days, correct?

12 **A.** That's right.

13 **Q.** And the rate of OUD was 1.2 percent for patients who
14 were treated with medium dose for more than 90 days,
15 correct?

16 **A.** Yes.

17 **Q.** And the OUD level was higher for patients with a high
18 dose treated more than 90 days, 6.08 percent, correct?

19 **A.** I see 6.1 percent, but maybe that's rounding.

20 **Q.** It may well be rounding, but okay. I pulled that out
21 of one of the tables.

22 **A.** Okay.

23 **Q.** But 6.1 percent is stated here. So, just so we're on
24 the same page, so it found a level of OUD incidence for
25 people treated more than 90 days as a high dose and that

1 came out to 6.1 percent, correct?

2 **A.** That's right.

3 **Q.** And when you talked last week about the 122 times, you
4 were using this number of the 6.08 percent, correct?

5 **A.** That's right.

6 **Q.** You weren't referring to these other numbers, the
7 numbers, for instance, for acute -- acute treatment of less
8 than 90 days of .12 percent? That's not what you were
9 referring to, correct?

10 **A.** The 122 times is comparing the high dose chronic group
11 to non-prescribed opioid group, but the other groups also
12 had an increase in the risk, including the group that you
13 mentioned first, the acute low dose group. They were more
14 than three times as likely to develop Opioid Use Disorder.

15 **Q.** So, but focusing on the percentages here, the study did
16 find a percentage of .12 percent of OUD when opioids were
17 used for less than 90 days at all dosage levels?

18 **A.** Right, which the authors mention in the discussion
19 translates to, you know, 98 million people are prescribed
20 opioids in the United States. So, that translates to a
21 major population impact.

22 THE COURT: Your Honor, I move to strike as
23 non-responsive.

24 THE COURT: Just a minute. Overruled. Go ahead.

25 BY MR. HESTER:

1 Q. So, but -- but let me -- let me just be clear, Dr.
2 Keyes, on what the findings were. So, the study found that
3 the incidence level of OUD when opioids were used for less
4 than 90 days at any dosage level was .12 percent, correct?

5 A. That's right.

6 Q. And the study also found that when opioids were used
7 for more than 90 days with a low or medium dose the
8 incidence of OUD was between .7 percent and 1.2 percent,
9 correct?

10 A. That's right.

11 Q. So, then meaning when opioids were used for more than
12 90 days at a low or medium dosage, 98.8 percent of the
13 patients did not develop OUD, correct?

14 A. That's right.

15 Q. And these findings from this study apply to West
16 Virginia, correct?

17 A. I think that -- I generally think that they would
18 generalize beyond the study sample.

19 Q. And so, you agree that the findings of this study, this
20 Edlund study that we're looking at, apply to West Virginia,
21 correct?

22 A. Yes.

23 Q. And the -- let me point you to Page 6 of the document,
24 please. At the top of the page, the Edlund -- Edlund and
25 the other authors state, "Actual frequencies of OUDs were

1 relatively low; that is, under 1 percent for four of the six
2 categories of opioid use."

3 Do you see that?

4 **A.** Well, that's not the whole sentence. The sentence
5 starts, "Although risks were high." It could be argued that
6 actual frequencies of OUDs were low.

7 **Q.** Well, okay. If you're going to -- if you're going to
8 add to my question, you need to put in the parenthetical,
9 too.

10 **A.** I'm sorry. I'll read the whole thing. "Although risks
11 as measured by ORs", which means odds ratios, "it could be
12 argued that actual frequencies of OUDs were relatively low;
13 that is, under 1 percent for four of the six categories of
14 opioid use."

15 **Q.** Yes. So -- so, we both are -- we see that sentence and
16 now I wanted to ask you a follow-up on the sentence, which
17 is it accurate to state that the frequency of OUD was under
18 1 percent for four of the six categories of opioid use,
19 correct?

20 **A.** That's right.

21 **Q.** And so, when we talk about the categories of opioid
22 use, there's six categories we're talking about? There's
23 three that could be more than 90 days and three that would
24 be 90 days or less, correct?

25 **A.** That's right.

1 Q. And the three in each bucket would be low, medium,
2 high, less than 90 days, low medium high 90, days or more,
3 or 91 days or more, correct?

4 A. That's right.

5 Q. So, that's what they mean by the four of the six
6 categories, correct?

7 A. Yes.

8 Q. Then it goes on in the next paragraph. There's a first
9 sentence that says, "Our findings have important clinical
10 implications, as they suggest that the risk of an incident
11 OUD is relatively small for an acute trial of opioids."

12 Do you see that?

13 A. I do.

14 Q. And, again, there they're referring to an acute trial,
15 meaning that any dosing level for less than 90 days, the
16 Edlund article characterized the risk of an incident OUD as
17 relatively small, correct?

18 A. That's what that sentence says. I believe it's more
19 contextualized in the -- in the following sentences.

20 Q. But the -- but Edlund did state in this article that
21 the risk of an incident OUD is relatively small for an acute
22 trial of opioids?

23 A. That sentence says that.

24 Q. And acute trial, again, meaning less than 90 days of
25 use?

1 **A.** That's right.

2 **Q.** Let me also ask you to look a few sentences further
3 down. It says, "Our data suggests that it is almost
4 meaningless to talk of a single rate of OUDs."

5 Do you see that?

6 **A.** That -- that's how the sentence begins, yes.

7 **Q.** Right. I just wanted to ask you about that clause.
8 And the point being made there is you can't talk about a
9 single rate of OUD associated with prescription opioids
10 because you need to know both the duration of treatment and
11 also the level of dosing, correct?

12 **A.** My interpretation of that sentence would be that OUD
13 risk does vary with dose and duration. I mean, certainly,
14 there are many public health studies that have assessed
15 overall OUD prevalence. And so, my interpretation of that
16 would be that the author is reporting that OUD risk varies
17 by dose and duration. So, there's not one particular number
18 of like this is how many OUD cases you're going to get.
19 But, certainly, in public health we report the prevalence of
20 OUD without always reporting dose and duration because it
21 really depends on the public health activity that you're
22 doing.

23 **Q.** But the point being made in this Edlund study is if
24 you're really going to be able to assess risks of OUD
25 associated with treatment with prescription opioids, you

1 need to know the dose and duration?

2 **A.** No. I don't think that that's how my interpretation of
3 that sentence would be. My interpretation would be that
4 Edlund and colleagues are saying that dose and duration are
5 major factors in determining the risk of OUD.

6 **Q.** Let me ask you, you're aware that the majority of
7 opioid prescriptions are for short-term therapy of less than
8 90 days, correct?

9 **A.** In what year?

10 **Q.** Let me ask you generally without reference to any
11 particular year. You're aware that the majority of opioid
12 prescriptions are for short-term therapy of less than
13 90 days?

14 **A.** It certainly would depend on the opioid therapy that
15 we're specifying. I haven't seen data on every opioid
16 therapy.

17 **Q.** So, you don't know one way or the other what level of
18 prescriptions are for short-term treatment as compared to
19 longer term?

20 **A.** Because you haven't specified the product that we're
21 talking about, I can't report on the average duration of
22 every opioid product.

23 **Q.** Do you have any understanding that there's a large
24 fraction of opioid prescriptions that are written for
25 short-term treatment of less than 90 days?

1 **A.** Yes, which is why this OUD number is so concerning.

2 **Q.** The -- I was asking about less than 90 days.

3 **A.** Right.

4 **Q.** And the point is that you're aware that there is a
5 substantial fraction of prescriptions that are written for
6 less than 90 days of treatment, correct?

7 **A.** Yes, which is -- yes. That's the problem with having
8 .12 percent incidence.

9 **Q.** The -- the -- and this is true even for patients with
10 chronic non-cancer pain? They're often prescribed opioids
11 for shorter durations, correct?

12 **A.** I don't know that.

13 **Q.** Let me ask you to look back at Edlund again. Again,
14 sticking on Page 6. He begins on the left-hand column, the
15 final paragraph. The first sentence says, "Although our
16 study was designed to study incidence of OUDs, it also
17 provides descriptive data on incident opioid use for chronic
18 pain." Do you see that?

19 **A.** Yes.

20 **Q.** And then it goes on in the next sentence to say, "At
21 35 percent, incident opioid use was not uncommon" -- I'm
22 sorry. I messed that up. "At 35 percent", comma, "incident
23 opioid use was not uncommon among individuals with new onset
24 of a CNCP episode."

25 Do you see that?

1 **A.** I do.

2 **Q.** And the reference to CNCP is chronic non-cancer pain,
3 correct?

4 **A.** Yes.

5 **Q.** And this study is focusing on the treatment of people
6 with chronic non-cancer pain, correct?

7 **A.** Right.

8 **Q.** And so, it indicates here that only 35 percent of the
9 population, 35 percent of the sample they studied, only
10 35 percent received an opioid prescription, correct?

11 **A.** 35 percent of people on the sample were prescribed an
12 opioid for chronic non-cancer pain; that's the question,
13 right?

14 **Q.** Yes, exactly.

15 **A.** Okay.

16 **Q.** That's -- that's what I meant to be asking you. In
17 other words, he was looking at a sample of people with
18 chronic non-cancer pain and he's reporting that only
19 35 percent of the sample received an opioid prescription,
20 correct?

21 **A.** I certainly wouldn't use the word only. That's a huge
22 number.

23 **Q.** I'm -- okay.

24 **A.** The word only isn't in the sentence. That's --

25 **Q.** I'll take out only.

1 **A.** Thank you.

2 **Q.** He -- he's looking at a sample of people with chronic
3 non-cancer pain and 35 percent of the sample received an
4 opioid prescription, correct?

5 **A.** Yes.

6 **Q.** And so, another way to put that is 65 percent of this
7 group that had chronic non-cancer pain was not prescribed an
8 opioid?

9 **A.** That's right.

10 **Q.** And then, he states in the next sentence, "However,
11 among the 35 percent who received opioids, only 5 percent
12 proceeded to chronic use."

13 Do you see that?

14 **A.** I do.

15 **Q.** And then he says, "And only 3 percent of these
16 proceeded to chronic use of high daily doses."

17 Do you see that?

18 **A.** I do.

19 **Q.** So, he does a little math for us in his parentheses.
20 He says, "Among the 35 percent who received opioids, the 5
21 percent who proceeded to chronic use represented 1.7 percent
22 of the sample", correct?

23 **A.** That's right.

24 **Q.** So, he's saying there that only 1.7 percent of the
25 overall sample was prescribed opioids for more than 90 days,

1 correct?

2 **A.** Again, the only is not the word I would use.

3 **Q.** He's got only in the sentence.

4 **A.** Not for the 1.7 percent.

5 **Q.** He's got only before 5 -- okay, we won't play. I'll
6 take out the word only. I won't inject any value judgment.
7 I'm just trying to clarify the word.

8 He's saying that 1.7 percent of the sample received an
9 opioid prescription for more than 90 days, correct?

10 **A.** That's right.

11 **Q.** And he's saying within that group the 1.7 percent that
12 received a prescription for more than 90 days for opioids, 3
13 percent of those people representing 0.1 percent of the
14 overall sample proceeded to chronic use at a high dose,
15 correct?

16 **A.** That's right.

17 **Q.** And he -- he then goes on in the next sentence to say,
18 "This is a steep selection process for patients achieving
19 chronic high dose therapy."

20 Do you see that?

21 **A.** Yes.

22 **Q.** And then he says, "Further, this selection process may
23 be even steeper now than when our study was conducted, due
24 to growing physician concerns regarding addiction."

25 Do you see that?

1 **A.** I do.

2 **Q.** And do you consider that to be a true statement?

3 **A.** I do believe that physicians are more concerned about
4 addiction now than they were in the 1990s and 2000s.

5 **Q.** And more so than they were at the time this article was
6 written in 2014?

7 **A.** Well, I think at the time the article was written in
8 2014 -- I mean, I'm agreeing with the author's statement
9 that there is a growing concern about addiction in 2014.

10 **Q.** And that's a growing concern within the medical
11 community as it gathered more data and information?

12 **A.** I think the medical and general public was increasingly
13 concerned about addiction.

14 **Q.** Let me ask you to look at another article, please.

15 MR. HESTER: Your Honor, may I approach?

16 THE COURT: Yes, you may.

17 BY MR. HESTER:

18 **Q.** Dr. Keyes, we've handed you a document marked DEF-WV
19 Exhibit 2524 headed Opioid Abuse and Chronic Pain
20 Misconceptions and Mitigation Strategies. Dr. Keyes, do you
21 have that document in front of you?

22 **A.** I do.

23 **Q.** And this is a 2016 paper written by Nora Volkow and
24 others published in the New England Journal of Medicine; is
25 that correct?

1 **A.** Yes.

2 **Q.** And you rely on this article in forming your opinions
3 in this case, correct?

4 **A.** I do.

5 **Q.** And Nora Volkow is the Director of the National
6 Institute on Drug Abuse, correct?

7 **A.** Yes.

8 **Q.** And let me point you to Page 1 of the document under
9 the heading for Source of the Opioid Epidemic. There's a
10 third sentence that reads, "In 2014 alone, U. S. retail
11 pharmacies dispensed 245 million prescriptions for opioid
12 pain relievers."

13 Do you see that?

14 **A.** Yes.

15 **Q.** Does that accord with your understanding?

16 **A.** It does.

17 **Q.** And then, it goes on to say, "Of these prescriptions,
18 65 percent were for short-term therapy of less than three
19 weeks."

20 Do you see that?

21 **A.** Yes. That's exactly why the Edlund article should be
22 so concerning.

23 MR. HESTER: Your Honor, I move to strike as
24 non-responsive.

25 THE WITNESS: I can explain.

1 THE COURT: Well, answer --

2 Mr. Farrell?

3 MR. FARRELL: Yeah. I think she should be
4 permitted to explain. She gave the -- she answered the
5 question yes and then offered an explanation.

6 MR. HESTER: I don't think -- Your Honor, she's
7 not explaining the question I asked her.

8 THE COURT: Right. The answer was non-responsive.
9 I'll strike it.

10 BY MR. HESTER:

11 **Q.** Dr. Keyes, I just wanted to ask about this sentence
12 that says, "Of these prescriptions, 65 percent were for
13 short-term therapy of less than three weeks."

14 Do you see that?

15 **A.** I do.

16 **Q.** And does that accord with your understanding that, in
17 this time frame of 2014, 65 percent of the opioid
18 prescriptions written in the country were for a duration of
19 less than three weeks?

20 **A.** Yes, that is my understanding.

21 **Q.** Also on the same page, it goes on to say that, "Chronic
22 pain not caused by cancer is among the most prevalent and
23 debilitating medical conditions, but also among the most
24 controversial and complex to manage."

25 Do you see that?

1 **A.** I don't. I'm sorry. It's on the first page?

2 **Q.** It's actually the first sentence of the whole article.

3 **A.** Oh.

4 **Q.** Didn't mean to trick you there. So, yeah, just so --
5 the article begins that way.

6 Do you see that?

7 **A.** Yes.

8 **Q.** That's a true statement, correct?

9 **A.** I think that -- I don't know -- I have not reviewed the
10 literature on what the most prevalent and debilitating
11 medical conditions would be. I actually might -- I might
12 have my own views on that.

13 Certainly, I would agree that chronic pain not caused
14 by cancer is prevalent and is a challenge to clinically
15 manage. I don't know that I would agree that it is the most
16 prevalent.

17 **Q.** Do you agree that chronic pain not caused by cancer is
18 a debilitating medical condition?

19 **A.** I agree that chronic pain not caused by cancer is a
20 debilitating medical condition.

21 **Q.** And do you see -- do you see further down on this same
22 first page, toward the bottom of the page, there's a
23 statement that says, "The major source of diverted opioids
24 is physician prescriptions?"

25 Do you see that?

1 **A.** Oh, I'm sorry. We're in a different section? Okay.

2 **Q.** Yeah, sorry. It's the last full paragraph on the page.
3 States, "The major source of diverted opioids is physician
4 prescriptions."

5 Do you see that?

6 **A.** I'm just trying to find it.

7 **Q.** It --

8 **A.** Yes. I see that.

9 **Q.** And that's a true statement, correct?

10 **A.** I mean, if I -- I would say a major source of diverted
11 opioids is physician prescriptions. I think there are other
12 major sources, but physician prescriptions is certainly a
13 major source of diverted opioids.

14 **Q.** Let me ask you to look at Page 4, please. There's --
15 over on the left-hand side, first full sentence on the page,
16 there's a reference -- well, I guess I should actually begin
17 by pointing you to the prior page, Page 3, and there's a
18 sentence on the right-hand side. "The repeated
19 administration of any opioid almost inevitably results in
20 the development of tolerance and physical dependence."

21 Do you see that?

22 **A.** Yes.

23 **Q.** And then it goes on to say over on Page 4, "These
24 short-term results of repeated opioid administration revolve
25 -- resolve rapidly after discontinuation of the opioid."

1 Do you see that?

2 **A.** Yes. They're referring to the intracellular signaling
3 cascades.

4 **Q.** And that accords with your understanding, correct?

5 **A.** I'm sorry. What -- I don't understand the question.
6 Whether intracellular signaling cascades resolve?

7 **Q.** When Dr. Volkow here says, "These short-term results of
8 repeated opioid administration resolve rapidly after
9 discontinuation of the opioid," that's a true statement,
10 correct?

11 **A.** There's a sentence in between the two that we haven't
12 discussed that I think is important for contextualizing the
13 short-term results of -- when she says "these short-term
14 results", she's referring to the predictable phenomenon
15 reflect contra-adaptations in opioid receptors and their
16 intracellular signaling cascades. So, that's what's
17 referred to as "these short-term results".

18 **Q.** And it accords with your understanding that those
19 results resolve rapidly after discontinuation of the opioid?

20 **A.** The intracellular signaling cascades, yes.

21 **Q.** Then, over on the right-hand side on Page 4, the last
22 full paragraph on the right-hand side says, "Unlike
23 tolerance and physical dependence, addiction is not a
24 predictable result of opioid prescribing."

25 Do you see that?

1 **A.** I see that.

2 **Q.** And then it goes on to say, "Addiction occurs in only a
3 small percentage of persons who are exposed to opioids."

4 Do you see that?

5 **A.** I do.

6 **Q.** And did you -- that's your understanding of what Dr.
7 Volkow -- how Dr. Volkow has characterized addiction risks
8 here?

9 **A.** I -- I agree that a small percentage of people who use
10 opioids develop Opioid Use Disorder and I think that's what
11 she's saying. I think you have to contextualize that with
12 the amount of opioid prescribing as we do in public health.

13 **Q.** But so, you would agree with the statement she makes
14 here?

15 **A.** Yes. There's numerous studies in the report that
16 demonstrate the same statement.

17 **Q.** Let me ask you to look over on the next page, Page 5,
18 please. And in the first full column on the left side
19 there's a sentence that begins, "However, we do know that
20 the risk of opioid addiction varies substantially among
21 persons, that genetic vulnerability accounts for at least 35
22 to 40 percent of the risk associated with addiction."

23 Do you see that?

24 **A.** I do.

25 **Q.** And does that accord with your understanding that

1 genetic vulnerability accounts for at least 35 to 40 percent
2 of the risk associated with addiction?

3 **A.** Yes.

4 **Q.** Okay. Dr. Keyes, we can put that one down for a
5 minute.

6 I want to turn back to discuss your testimony and the
7 estimates on the number of deaths caused by prescription
8 opioids in Huntington and Cabell County. So, just to set
9 the table here, you're not a Medical Examiner, correct?

10 **A.** Correct.

11 **Q.** And to estimate deaths attributable to prescription
12 opioids, you relied on data compiled by the CDC from death
13 certificates, correct?

14 **A.** That's right.

15 **Q.** And the CDC data is based on death certificates
16 prepared by authorities in each jurisdiction where the
17 deaths occurred, correct?

18 **A.** Yes.

19 **Q.** You did not look yourself at the underlying death
20 certificates, right?

21 **A.** That's right.

22 **Q.** But you are aware that there are circumstances where
23 more than one drug will be listed in a death certificate,
24 correct?

25 **A.** Yes.

1 Q. And, in fact, in Huntington-Cabell, there are many
2 polydrug overdoses, meaning overdoses where multiple drugs
3 are found in somebody's body at the time of death, right?

4 A. That's right.

5 Q. And so, for purposes of your calculations, if
6 prescription opioids were one of the drugs listed in the CDC
7 data, you directly contribute that death to prescription
8 opioids even if there were other drugs also identified as
9 contributing to the death, correct?

10 A. That is the reliable methodology of my field.

11 Q. But let me make sure I understand what you did. I
12 didn't ask whether it was reliable. I asked what you did.

13 A. Okay.

14 Q. And what you did was if a prescription opioid was one
15 of the drugs listed in the CDC data as contributing to
16 death, you directly attributed that death to prescription
17 opioids even if there were also other drugs also listed as
18 contributing to the death, correct?

19 A. Of course, yes, I did.

20 Q. So, if you have a death certificate that lists both
21 prescription opioids and heroin, the death certificate would
22 be coded in the CDC data as involving both prescription
23 opioids and heroin and you attribute that death directly to
24 prescription opioids?

25 A. Yes. And I can explain the reasoning why, if that

1 would be --

2 **Q.** I'll drill into that more later, but for now, I'm just
3 trying to set the table on what you did.

4 **A.** Okay.

5 **Q.** And, in fact, there could be circumstances where four
6 or five drugs would be listed on the death certificate as
7 contributing to the death and if one of them is a
8 prescription opioid, you would attribute that death directly
9 to prescription opioids?

10 **A.** Absolutely.

11 **Q.** So, to be clear, some portion of the deaths that you
12 categorize as directly attributable to prescription opioids
13 were coded by the Medical Examiner as also involving heroin
14 or illicit fentanyl?

15 **A.** Yes.

16 **Q.** And you don't actually know how many, correct?

17 **A.** In Cabell County or in West Virginia?

18 **Q.** In Cabell County?

19 **A.** You're asking if I know how many deaths had fentanyl --
20 had prescription opioids without one of these other codes?

21 **Q.** No. I was going at it the other way. So, if you had a
22 death certificate that listed prescription opioids, and
23 heroin, and fentanyl, all three were listed as contributing
24 to the death, I'm asking, you don't know how many of those
25 there were?

1 **A.** I think we do know that in the CDC data. I could -- we
2 -- we know it for -- I guess at the county level there might
3 not be sufficient numbers to estimate that directly.

4 **Q.** So, I mean, just to be clear on the methodology, you
5 could have a circumstance where there might be multiple
6 drugs listed, along with prescription opioids, that you
7 attribute that death directly to prescription opioids and
8 you don't know how many of those deaths there were that
9 might list multiple drugs alongside the prescription
10 opioids?

11 **A.** I think we do know how many list multiple drugs.

12 **Q.** For purposes of your death estimates in
13 Cabell-Huntington?

14 **A.** Oh, I -- is that knowledge knowable? Yes. But was it
15 relied upon for my methodology? No.

16 **Q.** Okay. So, just to make sure --

17 **A.** I apologize. I was not --

18 **Q.** No. Just so we're communicating here. So -- so, for
19 purposes of your analysis in Cabell-Huntington, when you
20 were attributing deaths to prescription opioids, you didn't
21 undertake to analyze how many of the deaths that you
22 directly attributed to prescription opioids also listed
23 other drugs as contributing to the death?

24 **A.** That was not part of the methodology.

25 **Q.** And so, you didn't do that?

1 **A.** I didn't -- it's not part of the methodology. I may
2 have done it -- I might have looked at that in developing
3 the methodology, but it's not part of the final number that
4 I derived.

5 **Q.** And so, we couldn't go back and figure that out from
6 the work you did?

7 **A.** No.

8 **Q.** And so, some portions of the death that you categorized
9 as directly attributable to prescription opioids also were
10 coded by the Medical Examiner as involving cocaine, for
11 instance?

12 **A.** Yes.

13 **Q.** You don't know how many were coded that way?

14 **A.** Off the top of my head, sitting here today, I don't,
15 but I don't believe that information is obtainable.

16 **Q.** But it wasn't part of your methodology?

17 **A.** No.

18 **Q.** And you also attribute a certain number of illicit
19 opioid deaths indirectly to prescription opioids, correct?

20 **A.** That's right.

21 **Q.** So, where you have a death where the soul cause is
22 listed as fentanyl on the death certificate, you indirectly
23 attribute a percentage of those deaths to prescription
24 opioids?

25 **A.** That's right.

1 Q. And this is based on your assumption of a gateway that
2 you discussed last week, correct?

3 A. Yes.

4 Q. So, I'm going to come back to that later, but I just
5 wanted to put a pin in it that that's the basis by which you
6 do this indirect attribution, correct?

7 A. Yes he.

8 Q. The NSDUH data, the government data, was your basis for
9 estimating deaths indirectly attributable to prescription
10 opioids, correct?

11 A. That's right.

12 Q. And the NSDUH data is limited to people who misused --
13 misused prescription opioids prior to heroin use, correct?

14 A. That's right.

15 Q. And so, with respect to the NSDUH data on prescription
16 opioid misuse, you don't know what percentage of those
17 people actually had a prescription for opioids, right?

18 A. Certainly, that is estimate-able [sic], and that's the
19 methodology I outline in the report, that there is this
20 quite large overlap. Most non-medical users also have a
21 prescription at some point in their lives.

22 Q. But you -- you don't know what percentage that is?
23 That wasn't something you developed as part of your
24 methodology, correct?

25 A. For the indirect attribution percentage, I used the

1 proportion of heroin users who started with non-medical
2 opioid use.

3 **Q.** And so, to be clear, the deaths that you're attributing
4 indirectly to prescription opioids did not have a
5 prescription opioid coded in the CDC data, correct?

6 **A.** The people I am indirectly attributing to prescription
7 opioids did not have a prescription opioid as a contributing
8 cause at the time of death.

9 **Q.** So -- so, the death certificate coded by the CDC
10 doesn't have prescription opioid listed as a contributing
11 cause of death in the ones that you indirectly attribute to
12 prescription opioids?

13 **A.** That's right.

14 **Q.** And when the death certificate does not list
15 prescription opioids as a contributing cause of death, the
16 Medical Examiner concluded that prescription opioids were
17 not a source of the death, correct?

18 **A.** A proximal cause of the death. It did not contribute
19 to the death as it occurred.

20 **Q.** So, when we have this indirect attribution, those all
21 involve death certificates where the Medical Examiner coded
22 the death as caused only by either heroin or illicit
23 fentanyl, correct?

24 **A.** Right. And I can provide a little bit of context for
25 that, if that would be helpful.

1 Q. I -- for right now, I'm just trying to set the stage on
2 what you did. And I've got that correctly, right?

3 A. That's correct. That's the methodology.

4 Q. And you've not examined the drug use histories of any
5 of the individuals whose opioid overdose deaths you count as
6 indirectly attributable to prescription opioids to determine
7 whether they ever used prescription opioids, correct?

8 A. It's an estimate based on the literature, so I did not
9 look at any particular death and their drug use history.

10 Q. So, let's take a step back and talk about how you
11 developed your report. You served your expert report on
12 August 3, 2020, correct?

13 A. Yes.

14 Q. You then served an errata three weeks later on
15 August 24, correct?

16 A. That's right.

17 Q. You were then deposed on September 15, correct?

18 A. Yes.

19 Q. And then you served a second errata a week after your
20 deposition on September 23, correct?

21 A. That's right.

22 Q. And between your report and the two errata, your
23 calculations on these death numbers changed, correct?

24 A. Yes.

25 Q. In your original report you estimated the number of

1 deaths directly and indirectly attributable to prescription
2 opioids using the methodology we just reviewed, you did a
3 direct attribution and an indirect attribution, correct?

4 **A.** Yes.

5 **Q.** And, in your original report, you reported that of the
6 105 opioid overdose deaths in Cabell-Huntington in 2018, 104
7 were directly attributable to prescription opioids, right?

8 **A.** Is the figure that's in the report in front of me based
9 on the original or the revised? I just want to make sure
10 that I'm giving you --

11 **Q.** I think what we have handed you is your original
12 report.

13 **A.** And do you have the revised that I can compare it to?

14 **Q.** Yes. We can try to come up with those. It may take us
15 just a minute, please.

16 **A.** Sure.

17 **Q.** Let me ask you before we -- before we get you the
18 documents, do you remember that you had to change the number
19 from what you had in your original report? You had to
20 revise it downward?

21 **A.** Well, there was two -- one, I had a typo and that was
22 -- I corrected it. And then, secondly, I also revised the
23 estimation. Could I have both?

24 MR. HESTER: May I approach, Your Honor?

25 THE COURT: You may.

1 MR. HESTER: I think if it's okay by counsel, this
2 was just to refresh Dr. Keyes' recollection. I wasn't
3 planning to introduce this as an exhibit.

4 THE COURT: You're refreshing her recollection on
5 the errata?

6 MR. HESTER: Yes.

7 BY MR. HESTER:

8 **Q.** Dr. Keyes, as I understand it, it would help you to
9 have the errata to refresh your recollection on the sequence
10 of events?

11 **A.** Yes.

12 THE COURT: You don't remember independently the
13 sequence of events?

14 THE WITNESS: I -- I remember this -- I just -- he
15 asked, well, the number was 105. And then, it was 104. And
16 then you arrived at -- I just don't remember the exact
17 numbers, but I remember the sequence of events.

18 BY MR. HESTER:

19 **Q.** So, Dr. Keyes, let me hand you two errata. And the
20 first errata that was submitted on August 24 and the second
21 errata from September 23, those will help refresh your
22 memory on the sequence?

23 **A.** They will. I'm sorry.

24 MR. HESTER: Your Honor, may I approach?

25 MR. ACKERMAN: Your Honor, may we get copies,

1 please?

2 MR. HESTER: Sure. Sorry.

3 BY MR. HESTER:

4 Q. So, Dr. Keyes, I think the first question I had for you
5 was in your original report you reported that of the 105
6 opioid overdose deaths in Cabell-Huntington in 2018, 104
7 were directly attributable to prescription opioids; is that
8 right?

9 A. That's right.

10 Q. And then that was an error? I think you've said that
11 was a mistake?

12 A. Well, not exactly. I can explain, if that's helpful.

13 Q. Well, you had counted every single death involving
14 fentanyl as a prescription opioid death?

15 A. So, that was the CDC's guidance. We followed the CDC's
16 guidance on categorizing prescription opioids. And then, I
17 decided that I was -- that that wasn't the best guidance to
18 use because the T40.4 deaths, which are the synthetic opioid
19 deaths, would include illicit fentanyl.

20 And so, I thought, well, I don't want to include that
21 as a prescription opioid because a lot of it might be
22 illicit. And so, that's why I made that revision. It went
23 from what the CDC recommends in terms of categorizing
24 prescription opioids to what I felt was a more accurate
25 reflection, which would be not including all of those as

1 prescription opioids because every fentanyl death is not a
2 prescription fentanyl death, to -- just to provide the
3 context there.

4 **Q.** So, you concluded that the first numbers weren't
5 correct, right?

6 **A.** Well, the first numbers are what the CDC recommends
7 that we do and I decided that that wasn't the best label.
8 To call those all prescription opioid deaths was probably
9 not the best way to estimate the direct attribution of
10 prescription opioids.

11 **Q.** Well, let's just make sure we got the context. You
12 started with 104 deaths that you directly attributed to
13 prescription opioids, correct?

14 **A.** That's right.

15 **Q.** Then you dropped the number that you directly
16 attributed to prescription down to 32, correct?

17 **A.** That's right.

18 **Q.** And then you dropped the number again to 20 and --

19 **A.** Yes, and I can explain. Okay, sorry.

20 **Q.** Dropped the number --

21 **A.** I'm excited about methods. I've got to --

22 **Q.** You dropped the -- you dropped the number again to 20
23 deaths attributable to prescription opioids in your second
24 errata, correct?

25 **A.** That's right.

1 **Q.** So, we went from 104 deaths directly attributable to
2 prescription opioids and in the original report down to 32
3 down to 20 deaths directly attributable to prescription
4 opioids, correct?

5 **A.** That's right.

6 **Q.** And let me ask you to look in particular at your second
7 errata. And this comes up with a number of -- as we've
8 discussed, 20 deaths that you attribute directly to
9 prescription opioids, right?

10 **A.** That's right.

11 **Q.** And that's based on the methodology that we discussed a
12 few minutes ago, correct?

13 **A.** If I could just qualify one part of what you're saying
14 that I'm realizing is a little bit inaccurate, is that
15 you're just talking about the 2018 deaths and that's where
16 the fentanyl issue becomes really apparent. Everything
17 before 2015, there really aren't any changes. It was just
18 when fentanyl happened that we had to change the methodology
19 to reflect the epidemiological situation.

20 So, not all of the numbers decreased in terms of the
21 direct attribution to prescription opioids, especially those
22 pre-2015 numbers. There really weren't any changes.

23 **Q.** Fair enough. So, I'm focusing -- I am focusing
24 principally on 2018 because 2018 is the number that
25 ultimately gets supplied to Dr. Alexander for purposes of

1 his abatement report, correct?

2 **A.** I don't know what --

3 **Q.** You don't know what's happened with the numbers you've
4 estimated?

5 **A.** I know that various other experts have relied upon
6 them, but I haven't -- I have tried to stay out of that.

7 **Q.** Okay. So, but in any event, I am -- it is fair I'm
8 focusing on 2018. And so, I want it to just be clear in the
9 record that it went from 2018 you started at 104 deaths
10 directly attributable to prescription opioids. You then
11 dropped the number to 32 deaths directly attributable to
12 prescription opioids. And then you dropped the number again
13 to 20 deaths directly attributable to prescription opioids
14 in 2018, correct?

15 **A.** That's right.

16 **Q.** And then you attribute 45 other deaths indirectly to
17 prescription opioids, correct?

18 **A.** Yes. The number went up. If we're talking about the
19 trajectory of indirectly and directly attributable. Because
20 the number of directly attributable went down, the number
21 indirectly attributable went up. There's kind of a -- a
22 correspondence between those two.

23 **Q.** So, again, just focusing on the 2018 numbers here, the
24 -- just so we have it for the record and it's clear, the --
25 you've indirectly attributed 45 overdose deaths to

1 prescription opioids based on the indirect attribution
2 methodology we discussed a few minutes ago, correct?

3 **A.** That's right.

4 **Q.** And the total number of deaths that you've analyzed is
5 105, correct? Those are the deaths for opioid overdoses in
6 2018, correct?

7 **A.** That's right.

8 **Q.** So, this means, applying your methodology, that you
9 attribute directly approximately 20 percent of the
10 opioid-involved deaths in 2018 to prescription opioids,
11 correct?

12 **A.** You're saying it would be whatever 20 plus 45 divided
13 by 105?

14 **Q.** Well, no. I was really focusing on the 21st, just so
15 the record is clear.

16 **A.** Oh.

17 **Q.** So, there's 105 opioid-related overdose deaths in 2018
18 in Huntington-Cabell that you've analyzed, right?

19 **A.** That's right.

20 **Q.** And of those 105, there are 20 that you directly
21 attribute to prescription opioids, correct?

22 **A.** That's correct.

23 **Q.** And that's based on the direct attribution methodology
24 we discussed a few minutes ago, correct?

25 **A.** Uh-huh, yes.

1 Q. And so then, in addition to those 20, there's another
2 45 deaths that you attribute indirectly to prescription
3 opioids?

4 A. Yes.

5 Q. Based on the methodology we discussed a few minutes
6 ago; is that right?

7 A. That's right.

8 Q. And so, from the 105 total deaths, total opioid-related
9 overdose deaths in 2018, we're left with, I believe, it's 40
10 deaths that you don't attribute either directly or
11 indirectly to prescription opioids, correct?

12 A. Just about, yeah.

13 Q. So, that means you have a -- you have a 40 percent or
14 so of the 105 total opioid-related overdose deaths you don't
15 attribute to prescription opioids, correct?

16 A. That's right.

17 Q. Either directly or indirectly, correct?

18 A. Yes.

19 Q. Did you say yes? I'm sorry.

20 A. Yes.

21 THE COURT: We need to pull the plug here, Mr.
22 Hester, when you get to a convenient stopping place.

23 MR. HESTER: All right. This is -- this is as
24 good a time as any, Your Honor.

25 THE COURT: All right. We'll come back at 2:00

1 and you can get up and walk around or do whatever you want
2 to do for two hours, Dr. Keyes.

3 THE WITNESS: Thank you.

4 (Recess taken)

5 THE COURT: Is Dr. Keyes in the courtroom?

6 Okay, Mr. Hester, you may continue, sir.

7 MR. HESTER: Thank you, Your Honor.

8 BY MR. HESTER:

9 Q. Good afternoon Dr. Keyes.

10 A. Good afternoon.

11 Q. Earlier today, you made a reference to pill mills; do
12 you recall that?

13 A. Yes.

14 Q. And I wanted to ask you in your report that you
15 submitted, your expert report that you submitted in the MDL
16 litigation, you stated that, quote, "Pill mills do not
17 explain in any significant way the expansion of opioid
18 prescribing and opioid-related harm in the U. S."

19 Do you recall saying that in your MDL report?

20 A. I do.

21 Q. And that's a true statement, correct?

22 A. Yes.

23 Q. Let me turn now to your estimate of the OUD population
24 in Huntington and Cabell County. And I'm going to do a
25 little bit on the board here.

1 And your view, Dr. Keyes, is that there is no
2 systematic way to count the OUD population, correct?

3 **A.** That's right.

4 **Q.** And so, because you can't actually count the OUD
5 population, you developed an estimate for it, correct?

6 **A.** Yes.

7 **Q.** And to estimate it, you divided the number of overdose
8 -- overdose deaths due to drugs in Cabell-Huntington in 2018
9 by a mortality rate; is that right?

10 **A.** By two mortality rates.

11 **Q.** Right. So, I will get into that.

12 **A.** Okay.

13 **Q.** And maybe we'll start with the simpler point first.

14 You -- you refer to a methodology that you described as
15 a multiplier method, right?

16 **A.** Yes.

17 **Q.** And if I can write this formula over here, I will ask
18 you, Dr. Keyes, so we're talking the same language, I hope.
19 So, the basic principle of the multiplier method is that if
20 you know the number of deaths due to drug overdose and you
21 know the mortality rate associated with a population of drug
22 users, you can back into the OUD number; is that right?

23 **A.** That's the basic idea.

24 **Q.** So, another way to put that based on the formula I put
25 up there, you could also multiply OUD, the OUD population,

1 by a mortality rate and that would give you a number of
2 deaths, right?

3 **A.** That's right.

4 **Q.** But, of course, in this case, we don't know the OUD
5 population, so you observe the number of deaths and then you
6 come up with a mortality rate and that's the way you
7 estimate OUD population, correct?

8 **A.** Well, not exactly because, as I discussed on Friday,
9 there were a number of adjustments that you need to make up
10 epidemiologically based on the current state of the
11 epidemic.

12 **Q.** So, but in the simple model -- and I'm going to get
13 into the adjustments.

14 **A.** Okay.

15 **Q.** But in the simple model, if you know the number of
16 deaths and you know a mortality rate, you can back into an
17 OUD population, correct?

18 **A.** That's right.

19 **Q.** So, you need to know two numbers. You need to know a
20 death number, which is due to drug overdoses, correct?

21 **A.** The number I used was deaths due to drug overdose.

22 **Q.** And then the other number would be the mortality rate
23 associated with the population of people who have OUD,
24 correct? Those are the two things you're trying to get to?

25 **A.** Generally, although there's not one mortality rate

1 because of -- I know we're going to get into it. I just
2 want to make sure that, for the record, it's stated the way
3 that I did it, which is that I used two mortality rates.

4 **Q.** Right. So, let's talk about the numbers you used but,
5 first, I wanted to be clear that because you're estimating
6 an OUD population, the accuracy of the death number and the
7 accuracy of the mortality number is extremely important to
8 coming up with an accurate OUD number, right?

9 **A.** Yes.

10 **Q.** And if either -- if you're off on the deaths or if
11 you're off on the mortality rate, you may be off on your OUD
12 estimate, correct?

13 **A.** Not exactly. The bioses would need to be working in
14 different directions in order for the OUD to be
15 mis-estimated. So, you could mis-estimate one, but as long
16 as you're mis-estimating the other in a similar direction,
17 then your OUD estimate may still be unbiased.

18 **Q.** Well, maybe I can take it more concretely in this case.
19 You came up with a specific number of deaths, so you know
20 that number that you have come up with, right, based on the
21 CDC data?

22 **A.** Yes.

23 **Q.** So, in the circumstance where you have a fixed number
24 for deaths, the question is, is your mortality rate
25 accurate, right? That's going to be the driver of the

1 accuracy, the OUD number, right?

2 **A.** Well, again, I mean, it would depend on if there's any
3 -- if there's any mis-classification of death, for example,
4 as long as that mis-classification is consistent in the
5 mortality at rate that you've estimated, then your OUD rate
6 would be unbiased.

7 So, I wouldn't agree with that as a blanket statement,
8 although there could be situations in which one or the other
9 estimate would -- would lead to a biased estimate of OUD.

10 **Q.** In this case, you came up with a number of 115 for
11 deaths; is that right?

12 **A.** Do you know what page that's on?

13 **Q.** 42 of your report, I think.

14 **A.** Okay. 115, yes.

15 **Q.** Right. So, let's drill into that 115 just a little
16 bit. Before lunch, we were talking about the fact that you
17 had looked at -- you had come up with a number of 105
18 opioid-related overdoses, correct?

19 **A.** That's right.

20 **Q.** For this calculation, to do your OUD estimate, you used
21 the number 115, correct?

22 **A.** Correct.

23 **Q.** So, you added ten more drug overdose deaths that were
24 not due to opioids, correct?

25 **A.** Well, I don't think that those two should be equated in

1 any way because this method relies on the all drug overdose
2 death number, not the opioid overdose death number. So, I
3 didn't add them. There happened to be 115 all drug overdose
4 deaths, of which 105 were opioid-related.

5 **Q.** Okay. So -- so, maybe I'll just put it the other way
6 around. In this 115, there are overdoses for non-opioid
7 drugs, correct?

8 **A.** That's right. That's what the method required.

9 **Q.** And so --

10 **A.** And I -- I can explain that, if you'd like.

11 **Q.** Well, let me walk through it and I think we'll get to
12 the right place. So, the 115 is going to include both
13 opioid-related deaths, but also drug overdose deaths due to,
14 for instance, methamphetamine or cocaine, correct?

15 **A.** Exactly.

16 **Q.** And so, it's going to include deaths caused by
17 methamphetamine, for instance, even if there was no opioid
18 involved at all?

19 **A.** And that's because the metaanalysis that it relies on
20 required that the OUD mortality rate be applied to the all
21 drug overdose category.

22 **Q.** But I just want to make sure that the method is clear.
23 You estimated or you came up with a count of 105 deaths that
24 are opioid-related, correct?

25 **A.** Right.

1 **Q.** And of those 105 that are opioid-related, we discussed
2 before lunch that there were 20 directly attributed to
3 prescription opioids under the method we discussed earlier,
4 correct?

5 **A.** Yes.

6 **Q.** And there are 45 that you attribute indirectly to
7 prescription opioids under the methodology we discussed
8 before, correct?

9 **A.** That's a different estimation process from this number
10 but, yes, in a different section of the report when I
11 estimate the attribution, that's what was --

12 **Q.** So, when we look at the 115, the number that you used
13 for this OUD calculation, it means that 50 of the 115 deaths
14 are not attributed by you either directly or indirectly to
15 prescription opioids, correct?

16 **A.** I haven't done that calculation. That was for -- I
17 haven't -- I haven't estimated out of the 115 the number
18 that would be indirectly attributable to prescription
19 opioids. Certainly, additional -- if you added the
20 additional overdose deaths, there would be a different
21 calculation for how many of them are indirectly attributable
22 to prescription opioids. So, it wouldn't be 50.

23 **Q.** Well, you have a number of 105. Are you saying there's
24 some different number that you haven't calculated for the
25 number of deaths attributable to --

1 **A.** No. I'm saying that if I were to calculate the number
2 of deaths that were attributable -- directly and indirectly
3 attributable to prescription opioids based on the 115, it
4 would be a different number than the number that I based
5 directly and indirectly attributable to prescription opioids
6 based on the 105.

7 **Q.** Do you have any reason to think that within this 115
8 death count that you used that there's more prescription
9 opioid deaths attributable than there was in the 105 we
10 discussed earlier when you went through the opioid-related
11 deaths?

12 **A.** Indirectly attributable, yes.

13 **Q.** Indirectly? So, you would say that there are some that
14 you would view as indirectly attributable in this 115, but
15 you haven't done that calculation?

16 **A.** I haven't -- yeah. I'm saying that hypothetically I
17 would have to do a different analysis to answer your
18 question, which I have not done, because these are all drug
19 overdose deaths including, you know, everything.

20 **Q.** Right. So, this 115 includes drug overdose deaths that
21 don't involve opioids at all?

22 **A.** Correct.

23 **Q.** So then, for the mortality rate, you relied on an
24 analysis that was published in 2019 in a journal called JAMA
25 Psychiatry, right?

1 **A.** That's right.

2 **Q.** So, let's take a look at that study.

3 MR. HESTER: May I approach, Your Honor?

4 THE COURT: Yes.

5 THE WITNESS: Did you also print out the
6 supplemental material because it's Figure 7-20 of the
7 supplemental material that I relied on for the death rate.
8 And so, that's a very important part of this discussion.

9 MR. HESTER: Let's try to see if we can straighten
10 it out.

11 THE WITNESS: Okay.

12 MR. HESTER: I'll do my best.

13 BY MR. HESTER:

14 **Q.** So, Dr. Keyes, we've handed you a document marked
15 DEF-WV Exhibit 2495. It has the title All-Cause and
16 Cause-Specific Mortality Among People Using Extramedical
17 Opioids, a Systematic Review and Metaanalysis.

18 Do you see that?

19 **A.** I do.

20 **Q.** And is this the paper that you relied on for the
21 mortality rate that you used to do the OUD estimate?

22 **A.** There were two mortality rates. One of them anchor --
23 well, both anchored in this paper, but one was -- I relied
24 on other information, as well.

25 **Q.** Right. So -- so in -- let's just be clear on this.

1 This is what you call the Larney study, right?

2 **A.** That's right.

3 **Q.** And it's called a metaanalysis because it analyzes the
4 results from other studies, right?

5 **A.** A metaanalysis takes a lot of studies and comes up with
6 a summary of all of those studies.

7 **Q.** And so, the Larney metaanalysis, if you look -- if you
8 look over at Page 4 of this paper under drug-related deaths,
9 there's a statement, "Across the three definitions for which
10 data were extracted, the pooled CMR was 0.52 per 100 per
11 person-years."

12 Do you see that?

13 **A.** I do.

14 **Q.** And that's one of the mortality rates that you used to
15 calculate OUD?

16 **A.** That's correct.

17 **Q.** So, let's put that on the board so we don't lose track
18 of it. So, I've written Larney = .0052. That's a correct
19 transition from the numbers in the report, right?

20 **A.** That's right.

21 **Q.** And so, the goal of this Larney study was to estimate
22 the mortality rate in people who engage in non-medical
23 opioid use; is that right?

24 **A.** Yes.

25 **Q.** And so, the rate that you used, this rate I've put up

1 of .0052, the rate that you used for your calculation is the
2 rate at which people using extra-medical opioids suffer
3 drug-related overdose deaths, not just opioid overdoses?

4 **A.** Sorry. I -- there is one correction I need to make to
5 your statement.

6 **Q.** Okay.

7 **A.** Which is that if you look at Figure 7-20 in the
8 supplemental materials, I went through each of the different
9 -- I think it's 56 different cohorts that informed that
10 death rate calculation to ensure that the majority of people
11 had OUD and not extra-medical opioid use.

12 **Q.** Well, okay, but --

13 **A.** And you -- you had said extra-medical opioid use, but
14 it's really OUD.

15 **Q.** Well, okay. Maybe -- maybe I can clean that up. So,
16 the Larney study includes people who did not have OUD,
17 correct? It includes mortality rates for people who did not
18 have OUD, correct?

19 **A.** I don't know what you mean.

20 **Q.** Let me point you to Page 2 of the document under the
21 heading for Inclusion and Exclusion Criteria.

22 Do you see that, right-hand column?

23 **A.** Sorry. Hold on.

24 **Q.** Page 2.

25 **A.** Yes.

1 **Q.** Are you with me there? And there's -- there's a third
2 sentence that says, "Cohorts did not need to be opioid
3 dependent or have Opioid Use Disorder to be included."

4 Do you see that?

5 **A.** I see that.

6 **Q.** And so, just -- I think your point is you looked at
7 this?

8 **A.** Right.

9 **Q.** I wanted to make sure I understand the Larney design
10 included studies of people who had overdoses who did not
11 have OUD, correct?

12 **A.** I suppose it's possible, but in the studies that I used
13 for my metaanalysis estimate for my OUD calculation, I made
14 sure to go through the studies to make sure that I wasn't --
15 that I was appropriately capturing my target population.

16 **Q.** Well, you didn't change the Larney number. You used
17 the Larney number as written in the paper, correct?

18 **A.** Right, which if you go to Figure 7-20 and you look at
19 those cohort studies, I think you'll see that they include
20 people who are in treatment for opioid dependence.

21 MR. HESTER: Your Honor, the witness is raising a
22 new point that was not disclosed in her expert report. I do
23 not believe this point has ever been made to us previously.
24 I mean, I can press on because I think I can get through
25 this, but I -- just for the record -- I believe this is not

1 something that Dr. Keyes stated in her report.

2 THE COURT: Well --

3 MR. HESTER: I'll -- I'll press on, Your Honor.

4 I'm not asking you to do anything.

5 THE COURT: Mr. Farrell, do you want to say
6 something?

7 MR. FARRELL: Well, the fact that this wasn't
8 asked before doesn't make it untrue.

9 THE COURT: Yes. It was in response to one of
10 your questions, Mr. Hester. So, you can go ahead.

11 MR. HESTER: Well, I would only say, Your Honor,
12 the expert, in my view, has an obligation to disclose her
13 methodology. This is complicated.

14 THE COURT: Well, that's true.

15 MR. HESTER: And it's going to get a little more
16 so as we work through it. And so, the fact that this is a
17 new piece of the methodology that wasn't disclosed, I must
18 say, is a little bit of a curve ball for us.

19 THE WITNESS: I'm sorry. It's not a new piece. I
20 -- I -- I can contextualize it further, but it's not a new
21 piece of methodology. It's all in the report.

22 MR. HESTER: I'll press on. I just wanted to
23 preserve my point.

24 BY MR. HESTER:

25 Q. So, Dr. Keyes, you recognized that the Larney study was

1 not enough or was not the only thing you could use for the
2 mortality rate, correct, because you recognized that there
3 is a fentanyl adjustment you needed to make, correct?

4 **A.** Yes.

5 **Q.** And so, let's just put that formula up on the board for
6 just a minute. So, you actually broke the mortality rate in
7 half -- or into two parts, not in half, but you broke it
8 into two parts.

9 So, you did OUD as a function of 115, which was your
10 death number, divided by a prescription opioid mortality
11 rate based on Larney?

12 **A.** Well, it's not a prescription opioid mortality rate.

13 **Q.** Okay. Or mortality -- what would be more accurate?

14 **A.** It would be --

15 **Q.** Larney?

16 **A.** Right. It would be the mortality rate for -- I suppose
17 I would -- I would characterize it as the OUD overdose
18 mortality rate for an -- aggregated across non-fentanyl
19 opioids. That's probably hard to write out.

20 **Q.** Do you have a clever way for me to abbreviate that?

21 **A.** Non-fentanyl.

22 **Q.** Okay.

23 **A.** Non-fentanyl.

24 **Q.** What if I put "NF"?

25 **A.** Sure.

1 Q. So, you broke it into two mortality rates, one
2 associated with non-fentanyl, and the other associated with
3 fentanyl?

4 A. That's right.

5 Q. Right? And then you made a determination that there
6 was a percentage breakdown in the deaths in 2018, correct?

7 A. Well, if I could just describe the methodology in a
8 little more detail. I took the two overdose death rates and
9 then I weighted them by the proportion of deaths by year for
10 which T40.4 or synthetic opioids were a contributing cause.
11 And so, in 2018, I'm sure you have the number with you.
12 It's probably 80-something percent, right?

13 Q. 84 percent.

14 A. Right.

15 Q. Does that sound right?

16 A. That sounds about right. And so, in previous years it
17 was lower, and then it increased over the course of the OUD
18 yearly estimation that I did.

19 Q. So, let's put that up on the board just so we don't
20 lose that. So, you had an 84 percent. Those were the
21 deaths that you construed as attributable to synthetic
22 opioids, correct, that percentage?

23 A. 84 percent of overdose deaths in 2018 were coded with a
24 T40.4 code, which is the synthetic opioid code.

25 Q. So, you concluded that, as you're looking at this 115

1 number, you would view 84 percent of those deaths as due to
2 synthetic opioids?

3 **A.** Yes. They had synthetic opioids as a contributing
4 cause.

5 **Q.** Well, and you viewed that as the contributing cause for
6 84 percent of the deaths, correct?

7 **A.** A contributing cause. There might have been other
8 drugs listed on the death certificate.

9 **Q.** But not prescription opioids, correct?

10 **A.** Prescription opioids could have been listed on the
11 death certificate.

12 **Q.** Well, but you weren't attributing these to prescription
13 opioids.

14 **A.** That was a different analysis. So, in this analysis,
15 I'm weighting the death rate, the OUD death rate for
16 fentanyl, by the proportion of deaths that had a fentanyl --
17 had T40.4 as an underlying cause.

18 They could have T40.1, T40.2, T40.-infinity, but they
19 at least had T40.4.

20 **Q.** So, I'm with you. So -- so, you're saying that you
21 viewed, from among this 115 deaths, 84 percent of them
22 you've had synthetic opioids listed as a cause?

23 **A.** That's right.

24 **Q.** So, that left 16 percent for non-fentanyl; is that
25 right?

1 THE COURT: Is synthetic opioid equivalent to
2 fentanyl or is there a difference? I'm a little bit
3 confused here.

4 THE WITNESS: There's a -- I can answer or --

5 MR. HESTER: Yes, please.

6 BY MR. HESTER:

7 Q. So, Dr. Keyes, synthetic opioids, that phraseology is
8 typically applied to illicit fentanyl, correct?

9 A. It's applied to any fully synthetic opioid. Fentanyl
10 would be one of which there's prescription varieties and
11 illicit varieties, but there's many other kinds of synthetic
12 opioids, as well.

13 Q. But, Dr. Keyes, just to be clear, the opioids that
14 you're focusing on here, these are -- these are illicit
15 fentanyl deaths, correct?

16 A. Well, that's another discussion that we should probably
17 have about the proportion of those that are prescription
18 fentanyl versus illicit, which I also provided an estimate
19 of. I'm sure we'll -- we'll get there.

20 Q. Sorry. You understood that the vast majority of this
21 84 percent of fentanyl deaths were illicit fentanyl,
22 correct?

23 A. Yes.

24 Q. And you attributed, in fact, three deaths out of 115 to
25 prescription fentanyl, correct?

1 **A.** That's right.

2 **Q.** So, if I do the math, and I'm not fast enough to do it
3 in my head, but it would be 84 percent times 115 would be
4 the fentanyl deaths. And then we would subtract 3 from that
5 to figure out how many you viewed as prescription fentanyl,
6 correct?

7 **A.** That seems reasonable.

8 **Q.** And putting it the other way around, therefore, if we
9 wanted to figure out how many were illicit fentanyl, it
10 would be 84 percent times the 115. And then, you would
11 subtract 3 from that for the prescription fentanyl deaths,
12 correct?

13 **A.** That's right.

14 **Q.** So, if we -- and as we discussed before, for the
15 non-fentanyl, you used Larney as your multiplier number,
16 correct?

17 **A.** Yes.

18 **Q.** And so that the math doesn't even get more complicated,
19 I'm going to ask you to help me. I've even got a calculator
20 here, Dr. Keyes.

21 MR. HESTER: Can I approach, Your Honor?

22 THE COURT: Yes.

23 BY MR. HESTER:

24 **Q.** And so, Dr. Keyes, we know that we're applying the
25 Larney number .0052 to the 16 percent that are non-fentanyl,

1 correct?

2 **A.** That's -- well, it's -- I think that's one way to
3 phrase it. It weights the denominator.

4 **Q.** Right.

5 **A.** By the -- it's .0052 times 16 percent.

6 **Q.** And maybe just to put it up here in the corner, I don't
7 want to do too much with it, but the point is, that you're
8 making is, it's .84 times your fentanyl mortality rate
9 plus .16 times the non-fentanyl?

10 **A.** Yes. That sounds about right.

11 **Q.** That's what -- that's what we need to come up with here
12 to do the proper weighting because we've got a non-fentanyl
13 mortality rate and a fentanyl and we need to weight them,
14 correct?

15 **A.** That's right.

16 **Q.** And sorry this is a little messy. But I think, if you
17 can help me with this, Dr. Keyes, we know -- we know the
18 Larney number. We know the .0052. And we know that -- the
19 16 percent. So, we can come up with what the NF number is,
20 correct? If you multiply -- if you multiply .1 --

21 **A.** Yes. We could come up with the NF number, yeah.

22 **Q.** Come up with that number --

23 **A.** Yes, because that would --

24 **Q.** You check -- check me. I think the weighted number is
25 .000832.

1 **A.** That's what I get, as well.

2 **Q.** Okay. So, we're going to do a little more math here.
3 Or maybe this is Algebra. So, its OUD is going to be 115
4 divided by .00832. That's the number you came up with,
5 right?

6 **A.** Yes.

7 **Q.** Oh, I'm sorry. I'm sorry, Dr. Keyes. I think I
8 dropped a digit. It should be .000832, right?

9 **A.** I already cleared it on my calculator, but --

10 **Q.** Can you do that again?

11 **A.** Sure. .0052 times -- 000832.

12 **Q.** Okay. And that -- so, that .000832, that represents
13 the weighted mortality rate for the non-fentanyl overdoses,
14 correct?

15 **A.** Yes.

16 **Q.** And then you needed a different mortality rate for the
17 fentanyl overdoses, correct?

18 **A.** That's right.

19 **Q.** And so, I'm just going to keep an "F" here for now and
20 we'll run through how you did that. Because the fentanyl
21 adjustment was what you needed to do, you couldn't use just
22 the straight Larney number; you had to adjust the Larney
23 number?

24 **A.** That's what I decided to do, yes.

25 **Q.** And for that purpose, you took the CDC data on overdose

1 deaths between 2011 and 2015; is that right?

2 **A.** That's right.

3 **Q.** And do you -- do you have handy in your report the CDC
4 overdose data or would it help you if I provided you with
5 those?

6 **A.** There's one specific article that I thought had a nice
7 figure. I'm sure you have it. I think --

8 **Q.** Is that the Hedegaard article?

9 **A.** Sounds right, but if you have the overdose death rate
10 from those years, we could --

11 **Q.** Yes. We can -- I think we can do that most
12 effectively.

13 MR. HESTER: May I approach, Your Honor?

14 BY MR. HESTER:

15 **Q.** Dr. Keyes, we've handed you two documents. They're
16 marked sequentially. And let me explain them just a little
17 bit and then I'll ask you to confirm that this looks right
18 to you.

19 There's DEF-WV 2586 headed Drug Overdose Deaths in the
20 United States, 1999-2018 written by Holly Hedegaard and
21 others.

22 Then there's DEF-WV 2587, which I can represent to you
23 is the appendix that goes along with the article --

24 **A.** Excuse me. Those articles are not referenced in the
25 report on that page.

1 Q. Yeah. I --

2 A. It's the Dowell article.

3 Q. I will -- are -- let me ask you if these -- so, Dr.
4 Keyes, are you familiar with these data briefs that are
5 published by the CDC?

6 A. I am.

7 Q. And I wanted to -- I think we can get to the same place
8 with this article.

9 A. I don't think so because I believe the Dowell article
10 -- these are for all drug overdose deaths and the Dowell
11 article, I believe, is opioid overdose deaths.

12 Q. Okay. Well, let me try that.

13 A. Okay.

14 MR. HESTER: May I approach, Your Honor?

15 THE WITNESS: Thank you.

16 MR. HESTER: Sure.

17 BY MR. HESTER:

18 Q. So, Dr. Keyes, are you able to -- well, maybe let me
19 set the table just a little bit more. You looked at CDC
20 mortality data to come up with your fentanyl adjustment; is
21 that right?

22 A. I did.

23 Q. And are you saying that the Dowell document is where
24 you found the CDC data?

25 A. Yes. The figure that is in Dowell for illicit opioid

1 overdose deaths from 1999 to 2015.

2 **Q.** So, you're looking -- maybe I should back up. I'm
3 sorry. I didn't set the record properly.

4 We've handed you DEF-WV Exhibit 2497 headed Underlying
5 Factors in Drug Overdose Deaths and, Dr. Keyes, this is the
6 document you were referring to just a minute ago, the Dowell
7 article?

8 **A.** Yes.

9 **Q.** And you were looking at the -- at the CDC -- at the CDC
10 data shown on Page 4 of this document?

11 **A.** Yes.

12 **Q.** And can you tell me which of the charts you used for
13 the CDC data?

14 **A.** If you look at the illicit opioid overdose death, which
15 is the top figure on Page 4.

16 **Q.** Yes.

17 **A.** And you compare the overdose death rate in 2011, which
18 is approximately two, and the overdose death rate in 2015,
19 which is approximately six per 100,000.

20 **Q.** And when you say "approximately", did you have the
21 exact data?

22 **A.** Yes. I looked at the underlying data that comprised
23 this figure, but you can see it pretty clearly goes from 2
24 to 6.

25 **Q.** And so, you used for this purpose the opioid-related

1 overdose deaths?

2 **A.** Illicit opioid overdose deaths.

3 **Q.** And the point you were making in making the fentanyl
4 adjustment was that the mortality rate you had from Larney
5 didn't actually capture the fentanyl phenomenon after 2011,
6 right, that there had been this increase in fentanyl deaths
7 and you needed to account for that in the mortality rate?

8 **A.** I was concerned that the mortality rate in Larney, as
9 applied to today's epidemic, was too conservative because we
10 know that people who use fentanyl have a higher risk of
11 overdose given the relationship between dose and duration
12 and overdose death.

13 **Q.** So, and what you did then for 2011, you took a baseline
14 level of synthetic overdose deaths and then you looked at
15 the change between 2011 and 2015; is that what you did?

16 **A.** Yes. It's called an interrupted time series method.

17 **Q.** So, let me point you back now to DEF-WV Exhibit 2587.
18 And if you look at the last page of this document, it shows
19 -- in the right-hand column it shows synthetic opioids other
20 than Methadone. It shows deaths per 100,000 for synthetic
21 opioids other than Methadone.

22 Do you see that?

23 **A.** I'm sorry. I -- so, this is --

24 **Q.** Defendant's exhibit 2587.

25 **A.** 2587.

1 Q. It's the -- the appendix?

2 A. Page 4?

3 Q. Yes.

4 A. Age-adjusted drug overdose death rates involving
5 stimulants, by type of stimulant?

6 Q. No. I'm on the -- I'm on the Page 4 -- I'm sorry --
7 Page 3. Age-adjusted drug overdose death rates involving
8 opioids, by type of opioid.

9 Do you see that?

10 A. I do.

11 Q. Are these the same data that you used?

12 A. No.

13 Q. They show -- they show deaths per 100,000 in the
14 right-hand column. Would that be deaths per 100,000 for
15 synthetic opioids; namely, fentanyl?

16 A. This data table has age-adjusted drug overdose death
17 rates involving opioid separated out by the type of opioid.

18 Q. Right.

19 A. I didn't rely on this to come up with the estimate that
20 I used in the OUD estimate. I used this estimation of
21 illicit opioid overdose deaths. And I can tell you why.
22 It's an important point.

23 Q. Why don't you explain why you did illicit overdose?

24 A. Because the estimate that we're trying to get to is the
25 probability that you die of an overdose given that you've

1 used an opioid that contains fentanyl. So, you wouldn't
2 want to use for that just the synthetic -- the total
3 synthetic opioid death rate because what you want is the
4 probability of a death given that you've used an opioid that
5 contains fentanyl. So, those would be two different
6 numbers.

7 And the illicit opioid overdose death rate is a closer
8 approximation of the probability that you die given that
9 you're using an opioid than the total number of T40.4 deaths
10 per 100,000. That would not be the right -- that would not
11 be the right quantity for the probability of death given
12 that you've used an opioid.

13 Because that's what Larney is estimating, right?
14 Larney is taking the total OUD population and estimating the
15 probability of death. And so, I need the total OUD
16 population and the probability of death if there's a
17 fentanyl in the opioid; not what the synthetic opioid
18 overdose death rate is, but the probability of death given
19 that you've used an opioid.

20 And that's why it's, in my opinion, more appropriate to
21 use the illicit opioid overdose death rate than just this
22 simple T40.4 synthetic opioid death rate.

23 **Q.** So -- so here, if we go back to the Dowell paper and
24 the Dowell paper shows roughly -- that in 2011 the illicit
25 opioid overdose deaths are roughly two -- is that what you

1 say?

2 **A.** About two per hundred thousand.

3 **Q.** You don't know it exactly?

4 **A.** Not off the top of my head.

5 **Q.** Do you have a way to find it?

6 **A.** With a computer, I can.

7 **Q.** What is the way you would find it?

8 **A.** You could -- I mean, they use the CDC data. So, you
9 could look up the CDC data.

10 **Q.** So, the Dowell data -- the Dowell paper is based on the
11 CDC data?

12 **A.** This -- this estimate is. They also have prescription
13 opioid sales and other -- the paper includes data other than
14 the CDC WONDER data, but I -- this estimate is based on CDC
15 WONDER data.

16 **Q.** And then -- and then you -- you ran that out to 2015,
17 correct?

18 **A.** Yes.

19 **Q.** You ran out the increase in illicit opioid overdose
20 deaths from 2011 to 2015, correct?

21 **A.** That's right.

22 **Q.** And so -- and, again, you don't know the precise number
23 for 2015, correct? You're looking at this chart. You don't
24 know the precise --

25 **A.** Right now, I'm looking at the chart, yeah. I don't --

1 I don't have that information stored in my working memory.

2 **Q.** And this Dowell paper is the only source you've cited
3 for the data to make this adjustment?

4 **A.** I cited the underlying CDC data that I verified the
5 numbers in Dowell with.

6 **Q.** And we could find in your work papers the precise
7 numbers?

8 **A.** I'm sure you could. I'm sure it's in the spreadsheets
9 that I sent.

10 MR. HESTER: So, may I have a moment to consult,
11 Your Honor?

12 THE COURT: Yes.

13 (Pause)

14 BY MR. HESTER:

15 **Q.** Dr. Keyes, I just want to run through the numbers that
16 you worked up to make sure we've got it all correct. So,
17 your approach, the approach you followed, was you multiplied
18 the Larney rate times 3, correct?

19 **A.** That's right.

20 **Q.** And that was based on your eyeballing that the Dowell
21 data showed about 3?

22 **A.** It's based on the Dowell data, which is based on the
23 CDC data.

24 **Q.** Now, in your report, you use the word "approximately".
25 You said it was "approximately a change of 3." Was it

1 exactly a change of 3 or approximately?

2 **A.** I would have to go and look at the -- the numbers
3 again.

4 **Q.** What's the reason that you used the word
5 "approximately" in your report?

6 **A.** I think I was just trying to provide a general overview
7 of my method.

8 **Q.** So, let me ask you just to confirm the numbers. So,
9 your approach was to multiply Larney times 3 for the
10 fentanyl adjustment, right?

11 **A.** That's right.

12 **Q.** And I think -- can you do the math for me, Dr. Keyes,
13 just to confirm? If we multiply Larney times 3, and then we
14 -- it would have to be Larney times 3 x .84.

15 **A.** Can I have a pen and scrap paper?

16 **Q.** Yes. Do you need some paper, too?

17 **A.** Yes, please.

18 **Q.** Okay.

19 **A.** So, we have 3 x 0.0052 and then we're multiplying
20 that by .84, right?

21 **Q.** Yes.

22 **A.** Okay. I get 0.013104.

23 **Q.** And then you're able to recreate the number, the final
24 OUD number that you came up with from that, correct?

25 **A.** I -- do you want me to --

1 Q. Yes. Could you do the final math? So, in other words,
2 let's just be clear for the record. You multiplied Larney
3 times 3, so it's $.0052 \times .84$. That becomes your fentanyl
4 mortality rate, right? Correct? And it's a weighted
5 fentanyl mortality rate?

6 A. That's correct.

7 Q. And then you add that together with the non-fentanyl
8 mortality rate?

9 A. That's right.

10 Q. And is -- are you able to recreate the exact number
11 that you came up with for your OUD estimate?

12 A. I am doing it right now. You've given me a calculator
13 and pen and math to do. This is like the best day.

14 Q. What could be better than this?

15 A. Okay. Yes. I've recreated the number.

16 Q. And the number is?

17 A. 8252.

18 Q. And that's -- that's the way you calculated the OUD
19 population for Huntington-Cabell, right?

20 A. That's right.

21 Q. Now, I asked you before about your point, your use of
22 the word "approximately". If -- if the approximation is not
23 exactly 3, but if the number -- if the multiplier here were
24 larger than 3 -- so, for instance, if the multiplier were a
25 larger number and I'm going to -- I'm going to do an example

1 just to work it through with you, okay?

2 And I'm just putting up here, just so we don't get
3 confused, 2015 unrounded. You ran this out to 2015. So,
4 you were looking at the change -- when you came up with your
5 three-times multiplier, you were looking at the change
6 between 2011 and 2015, correct?

7 **A.** Yes. I don't -- sorry. I'm not understanding what
8 "unrounded" means there.

9 **Q.** Well, I'll explain that.

10 **A.** Okay.

11 **Q.** I know that's my word and not yours.

12 **A.** Okay.

13 **Q.** So, let the record be clear that's my word I wrote out
14 just to help me and we can change it to something else.

15 **A.** Okay.

16 **Q.** But you used the word "approximately" and I just want
17 to ask you to work through a number with me and it's really
18 to assume something. It's not to say that it's right, but
19 it's to assume.

20 And I want you to assume that the approximate number is
21 actually rounded and that the real number is 3.875. And if
22 you assumed that, Dr. Keyes, if you assume that the real
23 number --

24 **MR. HESTER:** May I consult with my colleague for a
25 minute?

1 THE COURT: Yes.

2 (Pause)

3 BY MR. HESTER:

4 Q. I'm going to actually change my assumption, Dr. Keyes.
5 I want you to assume with me that the proper number is 3.27
6 times Larney. I want you to assume that. Can you run the
7 math for me on what that would be?

8 A. Sure. Looks like about 8,051, if I'm doing my math
9 right.

10 Q. I'm not sure that you are, Dr. Keyes.

11 A. Oh, no. I can try it again. Okay.

12 Q. So, you multiply --

13 A. So 0.0052×3.27 , right?

14 Q. Yeah. I mean .0327.

15 A. .0327? We're multiplying --

16 Q. Oh, sorry. You're right.

17 A. Okay.

18 Q. Sorry. So, it would be $3.27 \times$ this .0052?

19 A. So, that's .017004 --

20 COURT REPORTER: I'm sorry. Can you repeat that
21 number one more time?

22 THE WITNESS: Yes. .017004.

23 COURT REPORTER: Thank you.

24 THE WITNESS: And we're multiplying that number
25 then times .84, correct?

1 BY MR. HESTER:

2 Q. Yes, to create your fentanyl adjustment.

3 A. Yeah. So then, I get 0.01428336.

4 Q. .01428?

5 A. Yes.

6 Q. Yes.

7 A. Is that right.

8 Q. Yes. And so, that adds up to .01511 that you divide
9 into 115; is that right?

10 A. Well, let's just see. Then we've got 0052 x .16, which
11 is 0.000832.

12 Q. You've already got that one, yeah.

13 A. Right. Sorry. I'm just -- and then we're adding. So,
14 our denominator is 0.01511536; is that correct?

15 Q. Right. And you divide that into 115, correct?

16 A. Okay, got it. 7608.

17 Q. Now, let me ask you to make another assumption with me.
18 You ran -- you ran your numbers out to 2015 for making this
19 fentanyl adjustment, right? You looked at the period
20 between 2011 and 2015 and that was the period that you
21 looked at.

22 If you ran the fentanyl numbers out to 2018; in other
23 words, if you looked at the change in synthetic overdose
24 deaths over the whole -- over the period up to 2018, it
25 would also have it -- it would change the OUD numbers,

1 correct?

2 **A.** That wouldn't be the right methodology to use.

3 **Q.** I didn't ask you that.

4 **A.** Okay.

5 **Q.** I asked you if you did it, if you ran the --

6 **A.** I did not do that.

7 **Q.** And so, let me -- let me try to do that one. So, in
8 other words, you're measuring OUD numbers for 2018, correct?

9 **A.** That's right.

10 **Q.** You're trying to come up with an OUD population that
11 applies to 2018?

12 **A.** Yes.

13 **Q.** And so, if you looked at the change in synthetic
14 overdose deaths from 2011 to 2018 --

15 **A.** But I'm sorry. I don't understand why you would do
16 that.

17 **Q.** Well, I'm asking the "if". I'm asking you to assume
18 with me. I want to understand the sensitivity of the
19 numbers. The --

20 MR. FARRELL: Objection, Your Honor. The witness
21 has testified this is not proper methodology. So, as long
22 as the record is clear that she's using some methodology
23 proposed by Mr. Hester, but this is not a methodology that
24 she has adopted or is endorsing.

25 THE COURT: Well, you're using this to question

1 the methodology she did use, aren't you?

2 MR. HESTER: That's what I'm trying to do, Your
3 Honor. It's an assumption to test the methodology.

4 THE COURT: Mr. Farrell.

5 MR. FARRELL: I believe the witness just testified
6 that she would not use this for this purpose and attempted
7 to explain.

8 THE COURT: Well, I think it's proper cross
9 examination and I'll allow it. Go ahead.

10 MR. FARRELL: Can I also ask for a foundation to
11 where 3.27 comes from rather than just theoretical or
12 fictional?

13 MR. HESTER: Well, Your Honor, I don't think I'm
14 obliged to, but I think I will be able to set the foundation
15 for it. I -- I can do that, but I -- I would like to work
16 through the numbers first.

17 THE COURT: Go ahead.

18 BY MR. HESTER:

19 **Q.** If we -- if we looked at the period from 2011 to 2018
20 to derive your fentanyl adjustment and, during that period,
21 I want you to assume with me that the change reflected in
22 the CDC data is 6.36 --

23 **A.** Is that using the same definition that Dowell used --

24 **Q.** Yes.

25 **A.** -- in this, the illicit opioid overdose deaths?

1 Q. Yes. Now -- yes. And I'm going to set the foundation
2 with you, but I want you first to assume -- you know --
3 first of all, you know that fentanyl deaths have continued
4 to rise after 2015.

5 A. Yes. That's why we have the weighting procedure.

6 Q. Right. And so, what we see from 2011 to 2015 is some
7 increase in fentanyl deaths.

8 A. The start of the increase, which is very important for
9 the methodology.

10 Q. Well, okay.

11 A. Okay.

12 Q. And, in fact, the death rates increase, continue to
13 increase into 2018, correct?

14 A. The death rate did, but the probability of death given
15 use did not.

16 Q. Well, if there's more fentanyl being mixed into the
17 heroin supply and being mixed into the drug supply from 2018
18 as compared to 2017, or 2016, or 2015, that increases the
19 likelihood of death from fentanyl, correct?

20 A. No. That's the key to the methodology that I think I
21 would like to explain.

22 Q. Well, let me -- let me keep going on this.

23 MR. FARRELL: Objection, Your Honor. Can she
24 explain?

25 MR. HESTER: So, no. I don't think she's

1 answering my question.

2 MR. FARRELL: I'm sorry, Judge?

3 THE COURT: I'm going to let him continue and
4 finish and we'll see where we go. And she can be
5 re-directed on this, if you want to.

6 BY MR. HESTER:

7 **Q.** So, let me assume -- let me ask you to assume that if
8 you looked at the period 2011 to 2018 the change in the
9 numbers is not 3 times, but the change is 6.36.

10 **A.** But that's not what that number represents.

11 **Q.** I'm asking you to assume it, Dr. Keyes.

12 **A.** Right, but your -- it's based on assumptions that are
13 not what that number is representing.

14 **Q.** Dr. Keyes, you measured this approximately three times
15 by looking at this Dowell chart and seeing that there had
16 been a change in overdose deaths during the period from 2011
17 to 2015, right?

18 **A.** During the start of the increase of the fentanyl
19 period, which is why it is an appropriate methodology for
20 the parameter I'm trying to estimate, but going to 2018
21 would not be appropriate.

22 **Q.** I'm not asking you whether it's appropriate right now.

23 **A.** Okay.

24 **Q.** I'm asking you to test the assumption. And the way you
25 did this, just going back to Dowell, Exhibit 2497, is you

1 looked at the change between 2011 and 2015 in illicit opioid
2 overdose deaths, right?

3 **A.** Yes. It's a procedure called an interrupted time
4 series analysis.

5 **Q.** And you looked at the change between 2011 and 2015 to
6 figure out your three times adjustment?

7 **A.** That's right.

8 **Q.** If you looked at the change between 2011 and 2018,
9 there would be a larger change in illicit opioid deaths,
10 correct?

11 **A.** There would be a larger change, but it would not be a
12 correct change to use for that number. This is -- that's
13 why I didn't do it. I did this in 2018. I could have used
14 the 2018 numbers.

15 **Q.** Well, it would have shown your OUD number, right?

16 **A.** It would not have been an appropriate methodology to
17 use. It shrinks the OUD number anyway because I weight it
18 based on the proportion of cases that are T40.4.

19 So, if I used a bigger number for the multiplier, then
20 I wouldn't have weighted for the proportion of deaths that
21 are T40.4. The proper methodology that shrinks the OUD
22 number is to use the interruption of the time series given
23 the introduction of fentanyl and then weight that
24 probability by the probability of deaths that are T40.4.

25 **Q.** But you looked over a four-year period to figure that

1 out, to figure out your three-times multiplier? You looked
2 over a four -- year period?

3 **A.** That's right.

4 **Q.** I'm just asking you to work with me. Instead of
5 looking over a four-year period, I want you to look over a
6 seven-year period.

7 **A.** Okay.

8 **Q.** And if you look over a seven-year period and if you
9 assume that the change is 6.36 --

10 **A.** Okay.

11 **Q.** I want you to do that math for me.

12 **A.** However, I just have to say, if you do that, then you
13 shouldn't use the weights that I also provided. We should
14 just do 6.36×0.0052 and divide the 115 by that. It would
15 not be appropriate to do both of those things.

16 **Q.** This weighting that you used, this weighting that you
17 used, the 84 percent weighting for fentanyl was based on the
18 breakdown of deaths during 2018, correct?

19 **A.** That's right.

20 **Q.** Okay. Let's go back. I want you to assume that the
21 proper multiplier is $6.36 \times$ Larney. Are you able to do that
22 math for me?

23 **A.** 0.0052×6.36 is 0.033072.

24 **Q.** And then, what is the -- say that again, Dr. Keyes.

25 **A.** 0.033072.

1 Q. And then what is the OUD number that you estimate?

2 A. Should -- do you want me to include the weighting or
3 not include the weighting?

4 Q. Yes. I'm asking you to use the --

5 A. So, we're double weighting for --

6 Q. I'm asking you to use the same weighting you used based
7 on the 2018 deaths and I'm just asking you to use that and
8 is it -- can you tell me what the OUD number would be?

9 A. I get 3,391.9.

10 Q. 3,391; is that correct? That's what you calculated?

11 A. That's the calculation.

12 Q. Now, let me ask you to look back at the Dowell paper,
13 please. No, I'm sorry, not the Dowell paper. I want you to
14 look back at DEF exhibit WV 2587 and I want you to look at
15 the data table for figure 3, which is on Page 3 of this
16 document. Do you have that?

17 A. I do.

18 Q. And so, your point is that one should look at all
19 illicit opioid overdose deaths to figure out the CDC data?
20 In other words, we shouldn't just look at the synthetic
21 opioid number? We should also look at other illicit
22 opioids, correct?

23 A. Well, not exactly. The point is that the perimeter
24 that we're trying to estimate is the probability of death
25 given OUD and that the interruption of the time series

1 between 2011 and 2015 for illicit opioid deaths provides the
2 best approximation of that.

3 **Q.** So -- so, in your -- if you look back at the Dowell
4 paper, that's the one you said you used, correct?

5 **A.** That's right.

6 **Q.** And the Dowell paper has this line in the graph for
7 illicit opioid overdose deaths, correct?

8 **A.** Correct.

9 **Q.** And so, I'm trying to get to the precise data instead
10 of looking at this graph. And so, for that purpose, I want
11 to point you to DEF Exhibit 2587, Page 3.

12 **A.** This does not have the data that underlie that graph.
13 These are separated by each T code separately, but this
14 combines several T codes. So, we can't -- we can't compare
15 them directly. We can't get the exact number from Figure 3.

16 **Q.** I'm going to ask you to work with me again. If I look
17 at this exhibit, the data table for Figure 3, there's a --
18 there's a column for deaths per 100,000 for heroin, right?

19 **A.** Yes.

20 **Q.** And there's a column for synthetic opioid deaths other
21 than methadone, correct?

22 **A.** Yes.

23 **Q.** And so, if we add those two together, that's a measure
24 of illicit opioid deaths, right?

25 **A.** No. You can't add them together because they're not

1 mutually exclusive. As we previously talked about, there
2 can be multiple T codes listed on a death certificate.

3 **Q.** So, you could have circumstances where you have
4 multiple -- multiple causes of death listed in these death
5 certificates in there, so you can't add them together; is
6 that what you're saying?

7 **A.** That's what I'm saying.

8 **Q.** If you -- whether you agree with these specific numbers
9 or not, Dr. Keyes, the broader point here is that if the
10 mortality rate is too low, if the estimated mortality rate
11 is too low, your estimated OUD population is going to be too
12 high, correct?

13 **A.** That's right.

14 **Q.** And so, for instance, if your fentanyl adjustment is
15 too low, if this is lower than it should be, you're going to
16 be overestimating the OUD population?

17 **A.** This is why we do corroboration analyses and talk to
18 people in the county to try to corroborate.

19 **Q.** But can you answer my question first? If your fentanyl
20 adjustment is too low, then you're going to be
21 overestimating the OUD population, correct?

22 **A.** It's possible.

23 **Q.** Well, that's what would happen if your fentanyl
24 adjustment is too low.

25 **A.** The OUD estimate is a function of the underlying

1 denominator data. So, if the denominator changes, the OUD
2 estimate will change.

3 And so, if you use a different multiplier for fentanyl,
4 if your multiplier goes up, then the OUD population would go
5 down.

6 **Q.** But, in particular, if the fentanyl adjustment that
7 you've picked is lower than it should be, lower than what
8 the reality is, then you're going to overestimate the OUD
9 population under this formula?

10 **A.** Yes.

11 **Q.** That was fun. So, let's put that aside for a minute,
12 Dr. Keyes.

13 **A.** I'm happy to bring out the calculator anytime you have
14 another mathematical question.

15 MR. ACKERMAN: Mr. Hester -- or can we save
16 whatever's on that screen?

17 MR. HESTER: Yes. Yes.

18 MR. ACKERMAN: I just want to make sure we get it.

19 MR. HESTER: I want to make sure I press the right
20 buttons to save it.

21 MR. ACKERMAN: Before it disappears, exactly.

22 MR. HESTER: Confirm, right?

23 BY MR. HESTER:

24 **Q.** So, Dr. Keyes, putting aside this discussion that we've
25 just been having about the fentanyl adjustment and the

1 Larney data, I want to go back to your OUD estimate and, as
2 we discussed, the number that you estimate is 8,252 people
3 with OUD in Huntington-Cabell, correct?

4 **A.** That's right.

5 **Q.** And that's reflected, for instance, in your August 24
6 errata that I've given you, correct, at Figure 14?

7 **A.** Yes.

8 **Q.** So -- so, you have a total number of 8,252 individuals
9 with OUD that you estimate for Cabell-Huntington, correct?

10 **A.** That's right.

11 **Q.** And of that number, you allocate 5,800 of those OUD
12 cases directly to prescription opioids; you directly
13 attribute them, correct?

14 **A.** I do.

15 **Q.** And that applies your attribution methodology that we
16 discussed earlier?

17 **A.** That's right.

18 **Q.** And so, that means approximately 70 percent of the OUD
19 cases in your analysis are directly attributable to
20 prescription opioids?

21 **A.** I haven't done that math, but I trust that you have.

22 **Q.** I have. It's 5,800 divided by 8,252. It comes out to
23 about 70.82 percent. Sound about right?

24 **A.** That sounds about right.

25 **Q.** And then, you also estimate that 1,309 of the OUD cases

1 are indirectly attributable to prescription opioids,
2 correct?

3 **A.** That's right.

4 **Q.** So, that's approximately 16 percent of the OUD cases
5 that are indirectly attributable to prescription opioids and
6 that would be 1,309 divide by 8,252?

7 **A.** Yes.

8 **Q.** And, again, when you do this indirect attribution,
9 you're doing that based on the methodology we discussed
10 earlier today, correct?

11 **A.** Correct.

12 **Q.** And so, if you add up those OUD cases, the ones that
13 you directly attribute to prescription opioids and the ones
14 you indirectly attribute, the total is 7,109 OUD cases,
15 correct?

16 **A.** Yes.

17 **Q.** And that's 5,800 added to 1,309, correct?

18 **A.** Yes.

19 **Q.** So, out of the 8,252 OUD cases -- or OUD people or --
20 I'm sorry. Maybe I'll back up.

21 Out of that total number that you've estimated of 8,252
22 people with OUD, you attribute 7,109 to prescription opioids
23 either directly or indirectly, correct?

24 **A.** That's right.

25 **Q.** That means 1,143 OUD cases are not attributable to

1 prescription opioids in your methodology either directly or
2 indirectly, correct?

3 **A.** Correct.

4 **Q.** And that represents just about 14 percent of all the
5 OUD cases in Cabell-Huntington that you've estimated,
6 correct?

7 **A.** That's right.

8 **Q.** Dr. Keyes, I'd like to switch gears a bit to discuss
9 trends relating to prescription opioids. At Page 15 of your
10 report, and I think you have it there, you state that the
11 opioid prescribing rate in Cabell-Huntington -- no, in
12 Cabell County, sorry, was 186.6 prescriptions per 100
13 persons in 2011; is that right? Do you see it there on Page
14 15?

15 **A.** 186.6 prescriptions per 100 persons from 2006 to 2011.
16 So, yes.

17 **Q.** Right. So, I've got that right? The number you came
18 up with for 2011 for the prescribing rate in Cabell County
19 was 186.6 prescriptions per 100 persons?

20 **A.** That's right.

21 **Q.** And then, on the same page, you state that the opioid
22 prescribing rate declined at 92.1 prescriptions per 100
23 persons by 2018, correct?

24 **A.** That was the most recent year-end data available then.
25 There's since been 2019 data that has been released.

1 **Q.** And I'm really focusing on these numbers in your
2 report. You're showing more than a 50 percent decrease in
3 the level of prescriptions in Cabell County, prescription
4 opioids in Cabell County from 2011 to 2018, correct?

5 **A.** That's from the highest point to the lowest point, but
6 it's not from the pre-opioid epidemic point.

7 **Q.** Let me ask again.

8 **A.** Sorry.

9 **Q.** Between 2011 and 2018, you're showing more than a 50
10 percent decrease in the level of prescribing of prescription
11 opioids in Cabell County, correct?

12 **A.** Yes.

13 **Q.** And you're also aware that there's been a decline in
14 MME per person of prescription opioids in West Virginia
15 statewide, correct?

16 **A.** Yes.

17 **Q.** And in your report you state that the MME per person in
18 West Virginia decreased 2.4 percent from 2010 to 2015,
19 correct? That's at Page 15.

20 **A.** Yes. The decrease was slower than the U. S. average,
21 but it was 2.4 percent.

22 **Q.** So, the 2.4 percent decrease in the MME per person in
23 West Virginia from 2010 to 2015?

24 **A.** Yes.

25 **Q.** And then, from 2016 to 2017, the MME per person in West

1 Virginia decreased by 15.1 percent, correct?

2 **A.** That's right.

3 **Q.** You previously testified, Dr. Keyes, that the
4 non-medical use of prescription opioids means using them in
5 a way other than is prescribed by a doctor, correct?

6 **A.** Yes.

7 **Q.** And the non-medical use of prescription opioids is
8 declining in West Virginia, correct?

9 **A.** I believe it is.

10 **Q.** And in 2015 to 2016, I can point you to your report at
11 Page 40. In 2015 to 2016, 1.2 percent of
12 non-institutionalized West Virginians used opioids
13 non-medically in the prior month?

14 **A.** Well, I have to qualify that. That's based on the
15 National Household Survey of Drug Use and Health Data and
16 there's now -- that's an underestimate, we know, of
17 non-medical use and, in fact, there are some papers that
18 have recently come out suggesting that, nationally, we're
19 seeing increases in OUD; whereas, NSDUH is showing slight
20 declines. So, I would say that the NSDUH data shows that
21 the prevalence of non-medical use is slightly declining, but
22 we know that to be an underestimate.

23 **Q.** Well, let me ask you, your report states that available
24 evidence indicates that non-medical pain reliever use,
25 primarily opioids, is declining among non-institutionalized

1 mostly household populations in West Virginia overall from
2 1.2 percent of those in West Virginia in the sampling framed
3 reporting past month use which --

4 **A.** Right, but that section also qualifies --

5 COURT REPORTER: I'm sorry. Can you -- you were
6 overlapping. I'm sorry. Do you want to finish your
7 question so I can --

8 BY MR. HESTER:

9 **Q.** Yeah. I hadn't finished. Sorry. So, there was
10 decline, you state in your report, a decline in non-medical
11 pain reliever use among non-institutionalized mostly
12 household populations from 1.2 percent of those in West
13 Virginia in the sampling frame reporting past month use in
14 2015 to 2016 to .90 percent in 2017 to 2018, correct?

15 **A.** Yes.

16 **Q.** And your report also says that by 2017 to 2018, that
17 percentage had declined by 25 percent to 0.9 percent,
18 correct?

19 **A.** Can you -- which page of the report?

20 **Q.** Sorry. Page 40. So, I'm really just --

21 **A.** So, I say that the non-medical use of prescription --

22 COURT REPORTER: I'm sorry. Can you slow down for
23 me, please?

24 THE WITNESS: I'm sorry.

25 It says non-medical use of prescription pain relievers

1 has been relatively stable in recent years from 2.86 to 2.89
2 in 2016-2017 and 2017-2018 respectively. And reports of
3 heroin use in the past year among adolescents in West
4 Virginia from .7 to .9 percent in 2016-2017 and 2017-2018.

5 **Q.** I think you're focusing on a section dealing with
6 adolescents. I wanted to point you to the statement up
7 above in your report.

8 **A.** Oh, I see. So, we're focusing just on adults?

9 **Q.** Yes. So -- so, the prior paragraph in your report at
10 Page 40 is talking about adult non-medical use of pain
11 relievers; primarily opioids, correct?

12 **A.** Yes.

13 **Q.** And it states that the non-medical use of non-pain --
14 non -- sorry. Let me start over.

15 It states that the non-medical use of pain relievers;
16 primarily opioids, is declining among non-institutionalized
17 mostly household populations in West Virginia overall from
18 1.2 percent of those in West Virginia in 2015-16 to .9
19 percent in 20170-2018.

20 Do you see that?

21 **A.** I see that.

22 **Q.** And that's a correct statement of the data?

23 **A.** Well, not exactly because, as the next sentence
24 documents, Drug Use Disorder is increasing. So --

25 **Q.** I wanted to -- did you correctly state the data that I

1 read?

2 **A.** That sentence is -- you read the sentence correctly,
3 but it goes with the next sentence about Opioid Use
4 Disorder, which is what we're focused on.

5 **Q.** And the Opioid Use Disorder that you're describing in
6 the next sentence would include -- would include heroin and
7 fentanyl use, correct?

8 **A.** That's right.

9 **Q.** Let me ask you to look at another document, please.

10 MR. HESTER: May I approach, Your Honor?

11 THE COURT: Yes.

12 BY MR. HESTER:

13 **Q.** Dr. Keyes, we've handed you a document marked as
14 MC-WV 01864, which are the NSDUH 2017 state tables. Do you
15 have that in front of you?

16 **A.** I do.

17 **Q.** And this report contains statewide data from the
18 National Survey on Drug Use and Health, correct?

19 **A.** That's right.

20 **Q.** And you considered this report in forming your opinions
21 in this case?

22 **A.** I did consider it.

23 MR. HESTER: And let me ask Your Honor to move
24 this into evidence as a public record.

25 THE COURT: Any objection?

1 MR. FARRELL: Your Honor, I'm not quite sure what
2 the foundation of it is for other than the representation of
3 Mr. Hester --

4 MR. HESTER: Well, I believe Dr. Keyes said she
5 relied on it.

6 THE COURT: Well, if it's a public record --

7 MR. FARRELL: I'm not sure what it is.

8 BY MR. HESTER:

9 Q. Dr. Keyes, you're familiar with the National Survey on
10 Drug Use and Health, correct?

11 A. I am.

12 Q. And you reviewed data from NSDUH in your work, correct?

13 A. I did.

14 Q. And, in fact, you considered this report in your
15 materials? It's Reference 589 of your report, if you want
16 to look at it.

17 A. I considered many materials.

18 Q. This is one you would consider?

19 A. And this is -- this is one of hundreds.

20 MR. HESTER: Should I proceed, Your Honor, or do
21 you -- should I wait?

22 THE COURT: Well, have you laid the basis for it
23 under 803(8), Mr. Hester?

24 MR. HESTER: I -- I believe I've laid the basis,
25 Your Honor, that she's familiar with it. This is a document

1 she relied on. She's familiar with this data for purposes
2 of her work and I believe it's a public record published by
3 the U. S. Government.

4 THE COURT: Do you object to it, Mr. Farrell?

5 MR. FARRELL: Yes, Your Honor. Reliance by an
6 expert is not a basis alone for admission.

7 THE COURT: Well, I think that's right and I don't
8 think you've hit all the points you need to hit to get it in
9 under 803(8), Mr. Hester, so I'm going to sustain the
10 objection at this point and let you go ahead with your
11 questions.

12 MR. HESTER: All right. Thank you, Your Honor.

13 BY MR. HESTER:

14 Q. Dr. Keyes, if you look at Page 42 of this document,
15 Table 21 has data on Pain Reliever Use Disorder in the past
16 year by age group and state, correct?

17 A. That's right.

18 Q. And in West Virginia it shows the percentage of adults
19 over the age of 18 with Opioid Use Disorder in 2015 and 2016
20 was 0.91 percent, correct?

21 A. This is on the next page, right, 43?

22 Q. Yes. I think so, yes.

23 A. And, I'm sorry, what column are you referring to?

24 Q. It shows -- I was looking at the column over on the
25 right-hand side for people 18 and over in 2015 to 2016. It

1 shows a percentage of people with OUD in West Virginia
2 of .91 percent; is that correct?

3 **A.** No. This is a household sample. So, it excludes
4 anyone who is at high risk for Opioid Use Disorder. So, in
5 a low risk population, the prevalence as estimated by NSDUH
6 is .091.

7 **Q.** So, you're saying it doesn't include people who are
8 incarcerated or homeless?

9 **A.** For example.

10 **Q.** But it does include people who live in households?

11 **A.** It includes a sample of people.

12 **Q.** And let me ask you then to look at the NSDUH Report
13 from 2019.

14 **A.** Well, before we move on, we should note that the
15 decrease between 2015 to 2016 and 2016 to 2016 [sic] was not
16 statistically significant. So, I don't think it would be
17 accurate to say that it decreased.

18 **Q.** I haven't finished yet. So, I have one more I wanted
19 to show you.

20 MR. HESTER: Your Honor, may I approach?

21 THE COURT: Yes.

22 **Q.** Dr. Keyes, I've handed you Exhibit MC-WV 1866, which is
23 the NSDUH 2019 state data tables.

24 Do you see that?

25 **A.** Yes.

1 **Q.** And do you recognize this is a newer version of that
2 same report that NSDUH puts out annually?

3 **A.** I do.

4 **Q.** And the point you were making previously that NSDUH is
5 not comprehensive doesn't necessarily mean that comparisons
6 between years are not valid, correct?

7 **A.** Unfortunately, in the case of the NSDUH, it does, and I
8 believe across these years there was a change in the way
9 they asked the questions about prescription pain reliever
10 use. And so, they have explicitly stated on their website
11 that you cannot compare years.

12 **Q.** So -- so, you -- you believe you can't compare years
13 between NSDUH data?

14 **A.** Well, not all years, and it really depends on the
15 measure that you're looking at it depends on what year
16 you're trying to compare to what year. So, you just have to
17 be careful with the data because they change the questions
18 sometimes and they make those comparisons. Sometimes, you
19 can't compare them.

20 **Q.** What year did they change the data?

21 **A.** I don't -- off the top of my head -- I would have to go
22 to the NSDUH and website and look. I assume that it's
23 stated on there.

24 **Q.** Let me just ask you just one quick question on this and
25 then we'll move along. If you look at Page 44 of this

1 document, it states that the percentage of West Virginians
2 over the age of 18 with Opioid Use Disorder was .63 percent.

3 Do you see that?

4 **A.** Page 44?

5 **Q.** Yes.

6 **A.** That's Alcohol Use Disorder.

7 **Q.** Let me take you over to --

8 **A.** Or 43?

9 **Q.** 43. Sorry. Do you see the number for the column for
10 2018-2019? People 18 and over, the percentage with Opioid
11 Use Disorder listed as .63 percent?

12 **A.** The proportion of people in the NSDUH sample, yes.

13 **Q.** So, as between these two years, if you look at these
14 two documents together, and taking account of your point,
15 I'm just asking you the question, if you looked at these two
16 data sources together, it would show a decline in Opioid Use
17 Disorder of -- from .91 percent in 2015-2016 to .63 percent
18 in 2018-2019?

19 **A.** No. Unfortunately, you can't draw that conclusion from
20 these reports. What those reports show is -- the first
21 report shows no statistically significant decrease and the
22 second report shows no statistically significant decrease.
23 The P value is .178.

24 And you can't compare between the two reports. Even if
25 the methodology didn't change, they're not doing a

1 statistical test across those years.

2 So, as an epidemiologist, my conclusion would be you've
3 got two reports that both show there's been no change.

4 **Q.** Well, but it can't be quite right, Dr. Keyes, because
5 the P value here is only between two years. It's between
6 2018-2019 and 2017-2018, right? That's the way they measure
7 the P value?

8 **A.** Right, but there's no P value for 2015 to 2019.

9 **Q.** It hasn't been provided?

10 **A.** Right. You've got two non-significant P values.

11 **Q.** Your --

12 **A.** So, the only conclusion that you can draw here is
13 you've got two reports of four years and, in the first two
14 years, there's no change and, in the second two years,
15 there's no changes.

16 **Q.** But let me just make clear one point. The P values
17 that are reflected, for instance, in this document we're
18 looking at right now, which is Exhibit 1866, and we're at
19 Page -- I guess 43 of this document, those -- the P values
20 shown there is comparison between the two years of data that
21 are shown. It's between 2017-2018 and 2018-2019, right?

22 **A.** That's right.

23 **Q.** It doesn't provide a P value for the data between 2015
24 and 2018?

25 **A.** Which is why it would be inappropriate to conclude that

1 there would be a change over time documented here.

2 **Q.** The P value could be computed, correct, for that longer
3 period?

4 **A.** You'd have to look and see whether that would be
5 appropriate based on the NSDUH data if there had been a
6 change in measurement.

7 **Q.** If there hasn't been a change in measurement, you could
8 look at the P value between a longer period of time that's
9 just not provided here, correct?

10 **A.** Yeah. One could do that. And, theoretically, one can
11 look at changes over a longer period of time.

12 **Q.** Next, I'd like to talk a little bit more about --

13 THE COURT: It may be time for a break, Mr.
14 Hester.

15 MR. HESTER: Yes. That's a good time, Your Honor,
16 a very good time.

17 THE COURT: Okay. Let's take about ten minutes.

18 (Recess taken)

19 (Proceedings resumed at 3:42 p.m. as follows:)

20 THE COURT: Okay.

21 MR. HESTER: Thank you, Your Honor. May I
22 approach?

23 THE COURT: Yes.

24 BY MR. HESTER:

25 **Q.** Dr. Keyes, I've handed you a document marked

1 Defendants' West Virginia 2647. It's entitled
2 "Associations of Non-Medical Pain Reliever Use and
3 Initiation of Heroin Use in the United States."

4 Dr. Keyes, have you seen this document before?

5 **A.** Yes.

6 **Q.** And I take it this is a document you rely on in your
7 report; correct?

8 **A.** It is.

9 **Q.** And under the heading of Author Affiliation it says
10 that Pradip K. Muhuri and Joseph C. Gfroerer are with the
11 Substance Abuse and Mental Health Services Administration,
12 U.S. Department of Health and Human Services, Rockville,
13 Maryland.

14 Is that your understanding as to the author
15 affiliations?

16 **A.** I don't see here their affiliations.

17 **Q.** If you'd look at Page 16.

18 **A.** Oh.

19 **Q.** I'm sorry. I should have pointed you to this page, Dr.
20 Keyes.

21 **A.** I see.

22 **Q.** So it states that Pradip Muhuri and Joseph Gfroerer are
23 with the Substance Abuse and Mental Health Services
24 Administration of the Department of Health and Human
25 Services. Do you see that?

1 **A.** I do.

2 **Q.** Is that consistent with your understanding?

3 **A.** I don't know them and I, I -- but I have no reason to
4 believe otherwise. I believe -- I'm sure -- I would
5 assume -- I have no reason to know that what is stated here
6 is not the case.

7 **Q.** And as the title of this article suggests, the article
8 looked at the relationship between non-medical opioid use
9 and heroin initiation; is that right?

10 **A.** Yes. They measured non-medical -- the, the NSDUH data
11 that we've been talking about only measures non-medical
12 data.

13 **Q.** So this paper was looking at the association between
14 non-medical use of prescription opioids and heroin use;
15 correct?

16 **A.** That's right.

17 **Q.** It wasn't looking at the relationship between medical
18 use of prescription opioids and heroin use?

19 **A.** Well, that's, that's -- it actually is because of the
20 overlap in those two groups. We know that most non-medical
21 users also obtain prescriptions medically.

22 **Q.** Yes. But, but the point here is that somebody might
23 obtain some prescription opioids medically, but they are
24 viewed as non-medical users for purposes of this study;
25 correct?

1 **A.** They at least used opioids once non-medically as far as
2 I think that we could say based on what is assessed in the
3 study. But most non-medical users have also used medically.

4 **Q.** Let's be clear on the terminology here. When, when you
5 speak about a non-medical user, they might have had a
6 prescription or they might have a prescription, but the
7 focus of a study like this is on people who are using
8 prescription opioids non-medically; correct?

9 **A.** They are at least using non-medically. They may also
10 be using medically. And, in fact, because those two
11 populations overlap, we can -- they're not only using
12 non-medically I guess is what I'm saying.

13 **Q.** They might be using some opioids medically, but they're
14 also using opioids, prescription opioids non-medically;
15 correct?

16 **A.** That's right.

17 **Q.** And they're not included in the survey unless they are
18 engaged in at least some non-medical use of prescription
19 opioids; correct?

20 **A.** Exactly.

21 **Q.** And, so, -- and it's reflected in the title of the
22 document. They're looking at the relationship or the
23 association between non-medical use of prescription opioids
24 and heroin use; correct?

25 **A.** That's right.

1 **Q.** If you look at -- if you look at Page 1 of this
2 document in the abstract in the left-hand column, there's
3 a -- there's two statements.

4 One statement is, "Four out of five recent heroin
5 initiates previously used non-medical prescription --"

6 Actually, I should back up to make it clear we're on
7 the same language.

8 Do you see the references throughout this paper to
9 NMPR?

10 **A.** Yes.

11 **Q.** And that means non-medical prescription pain relief,
12 reliever use; correct?

13 **A.** That's right.

14 **Q.** And, so, that's what they're talking about here when
15 they say NMPR; right?

16 **A.** That's right.

17 **Q.** So it states in the, in the abstract, "Four out of five
18 recent heroin initiates previously used NMPR."

19 Do you see that?

20 **A.** I do.

21 **Q.** And is that the statistic that you cited in your prior
22 testimony?

23 **A.** There are many studies that show a similar estimate.
24 This is one of them.

25 **Q.** And then it goes on to say, "However, the vast majority

1 of NMPR users have not progressed to heroin use."

2 Do you see that?

3 **A.** I do.

4 **Q.** And does that accord with your understanding that the
5 vast majority of people who use prescription opioids
6 non-medically do not progress to heroin use?

7 **A.** Yes.

8 **Q.** And then it goes on to say only 3.6 percent of
9 non-medical prescription users had initiated heroin use
10 within a five-year period following their first non-medical
11 prescription opioid use. Do you see that?

12 **A.** I see that's what is written.

13 **Q.** And, and does that accord with your understanding?

14 **A.** I mean, 3.6 percent initiating heroin use is a -- quite
15 a large transition probability. So I guess I would only --
16 I would take issue with the word "only." 3.6 percent is a
17 lot of heroin.

18 **Q.** I don't think that answered my question. My question
19 was: Does it accord with your understanding that only
20 3.6 percent of people who are using prescription opioids
21 non-medically initiated heroin use within the five-year
22 period following their first non-medical use of prescription
23 opioids?

24 **A.** I believe that's what this study found if that's the
25 question.

1 **Q.** And, so, that means that putting it the other way
2 around, 96.4 percent of the non-medical prescription pain
3 reliever users did not use heroin within five years of their
4 first initiation of non-medical use of prescription opioids?

5 **A.** That's right.

6 **Q.** So I'm going to start a new board.

7 We have this one saved; correct?

8 So, Dr. Keyes, I've written on the board here
9 "gateway." And the first thing I wanted to do was put up
10 the number that we just discussed which was that
11 96.4 percent of non-medical users do not transition within
12 five years of first non-medical use. I want to just put
13 that up as a reference so we don't lose it.

14 **A.** In the household sample if you would add that, please.

15 **Q.** And that, that 96.4 percent, as we just discussed,
16 reflects the finding of this Muhuri article; correct?

17 **A.** That's right.

18 **Q.** And you make the same observation in your own report at
19 Pages 47 to 48 of your report if you want to look at your
20 report. You state that the absolute risk of transitioning
21 to heroin, given prescription opioid use, is relatively
22 small. Do you see that?

23 **A.** What page?

24 **Q.** 47 to 48 of your report.

25 **A.** I say a small but significant proportion of individuals

1 who use prescription opioids progress to heroin use.

2 **Q.** I was looking for the one -- I guess it's actually at
3 the top of, top of Page 48.

4 You say, "The absolute risk of transitioning into
5 heroin, given prescription opioid use, is relatively small."

6 Do you see that?

7 **A.** Well, could we read the whole sentence just for
8 context?

9 **Q.** No. I wanted to focus on that clause first. And I
10 wanted to focus on the fact that you state, "The absolute
11 risk of transitioning to heroin, given prescription opioid
12 use, is relatively small."

13 Do you see that?

14 **A.** I think out of context it's not really interpretable
15 because you have to look at the whole sentence which
16 includes the risk ratio estimate and the public health
17 burden. So out of context, one clause is not really
18 interpretable.

19 **Q.** Well, I wanted to ask you the basis for your statement,
20 "The absolute risk of transitioning to heroin, given
21 prescription opioid use, is relatively small."

22 What's the basis for that statement?

23 **A.** I think the studies that I cite in the report are the
24 basis.

25 **Q.** And Muhuri would be one of those that you rely on for

1 that purpose?

2 **A.** Muhuri is one of several studies.

3 **Q.** Let me put that on the board. I wrote "absolute risk
4 of transition small" to reflect that statement from your
5 report, Dr. Keyes.

6 **A.** The first part of the sentence is that the number of
7 individuals who use prescription opioids is approximately
8 seven times larger than the number who use heroin. So
9 that's probably an important point on that too. The point
10 is that while the absolute risk is small, the population
11 prevalence is large.

12 **Q.** In other words, your point is prescription opioids are
13 widely used as medicines in this country; correct?

14 **A.** That's right.

15 **Q.** And, in fact, the data we looked at previously today
16 reflected that almost a third of adults in 2014 received a
17 prescription for opioids; correct?

18 **A.** I believe you said 245 million.

19 **Q.** Actually, I may be low. So that could be more than --
20 it could be over 60 or 70 percent of the population of the
21 country; right?

22 **A.** That's right.

23 **Q.** So, in other words, the point is there's a large volume
24 of prescription opioids being prescribed by doctors in their
25 judgment of medical needs; correct?

1 **A.** There's a large supply of opioids. That's certainly
2 the case.

3 **Q.** Well, and that's being prescribed by doctors who are
4 prescribing them to patients; correct?

5 **A.** Some of them are being prescribed by doctors, correct.

6 **Q.** Well, most of them are being prescribed by doctors;
7 correct?

8 **A.** Yes, most of them are being prescribed by doctors.

9 **Q.** And so, and so your point is it's a large volume of
10 opioids because a large percentage of the country is being
11 treated with opioids?

12 **A.** Right. So if there's a small risk -- it's sort of like
13 smoking and lung cancer which I think I cite in the, in the
14 report.

15 The prevalence of lung cancer is much lower than the
16 prevalence of heroin use. And there's a lot of smokers in
17 the U.S. So most smokers don't develop lung cancer. And,
18 in fact, many more people use prescription opioids and
19 transition to heroin use than smoking and get lung cancer.
20 So you can't really look at the absolute risk in a vacuum.
21 You have to look at the prevalence as well.

22 **Q.** But the, but the point is if you have an extremely
23 large percentage of our country that is using prescription
24 opioids for medical purposes, there could be some percentage
25 of people who develop OUD as a consequence; correct?

1 **A.** Right. So if you take the 245 million number, for
2 example -- and I think you said that 65 percent are of short
3 duration?

4 **Q.** Yes.

5 **A.** I mean, we could work that through. That, that would
6 be 160 million people on short duration. And with an event
7 rate of .12, that's 200,000 people a year developing OUD
8 from short duration opioids.

9 **Q.** Or put it the other side, put it the other way around.
10 It also suggests the fact that 245 million people receive
11 prescriptions in a given year for opioids reflects a broad
12 scale judgment by doctors about prescribing opioids to treat
13 pain; correct?

14 **A.** There is a lot of opioid prescribing in the U.S. And,
15 therefore, small risk translates to big population changes.
16 And, so, yes, there is a vast over-supply of prescription
17 opioids in the U.S. And the majority of those people will
18 not have a problem related to opioids.

19 But when you have 200,000 people a year -- and that's
20 just the 160 million who are prescribed for less than three
21 weeks. We've got 85 million, based on what you cited
22 earlier, that are prescribed for chronic conditions where
23 the event rate is much higher. And that doesn't include
24 non-medical use.

25 **Q.** But I'm asking, I'm asking the point the other way

1 around. I'm, I'm trying to confirm that when you see a very
2 large volume of opioids being prescribed, it reflects a
3 widespread judgment by the medical community about the
4 appropriateness of those prescriptions.

5 **A.** I don't think it necessarily reflects a judgment about
6 the appropriateness. I think it reflects a, a decision
7 based on the information at hand, of which the information
8 can change.

9 **Q.** Well, you, you testified previously that the decisions
10 made by doctors are overwhelmingly in good faith. The
11 prescribing decisions on -- related to opioids are
12 overwhelmingly in good faith. Correct?

13 **A.** They're in good faith based on the information that's
14 available.

15 **Q.** And so, and so when the doctors are acting in good
16 faith to prescribe that volume of pills, it reflects a
17 widespread judgment by doctors about the appropriateness of
18 that prescribing behavior; correct?

19 **A.** I don't know that I would conflate those two
20 statements.

21 **Q.** So let's talk a little bit about how someone actually
22 transitions from prescription opioid use to heroin use.

23 First of all, all of the studies that you've cited in
24 your report in support of your opinion regarding the
25 connection between prescription opioids and heroin are

1 measuring an association between the misuse of prescription
2 opioids and heroin use; correct?

3 **A.** The studies that I cite in the report include medical
4 use followed by transition to heroin.

5 **Q.** That's not, that's not what I asked you. I asked you
6 the question: All of the studies you've cited in support of
7 your opinion regarding the connection between prescription
8 opioids and heroin all measure an association between misuse
9 of prescription opioids and heroin use; correct?

10 **A.** Incorrect.

11 **Q.** Let me ask you to look at your report, please, Page 37.
12 I'm trying to make sure I've got the right quote for you,
13 Dr. Keyes.

14 MR. HESTER: May I consult just a minute, Your
15 Honor, with my colleague? I'm sorry.

16 (Pause)

17 BY MR. HESTER:

18 **Q.** Dr. Keyes, I'm trying to find a statement -- a page
19 in your report. I'm going to read you a quote and see
20 if this is accurate.

21 **A.** Do you have a page number?

22 **Q.** I'm trying to find it.

23 Let me read this to you, Dr. Keyes. I have this in my
24 notes. I'm going to find the page for you, so I will find
25 this page reference. But let me read this and see if this

1 sounds correct to you.

2 "I reviewed 16 studies that found that individuals who
3 use prescription opioids non-medically have higher rates of
4 injecting and snorting heroin than individuals who do not
5 use prescription opioids even after controlling for health
6 and mental health as well as demographics."

7 Is that correct?

8 **A.** Well, I think in the context in that paragraph, I also
9 talk about the studies of medical users. Many of the
10 individuals in those studies were medical users.

11 **Q.** Well, we've gone through this before. Somebody could
12 be a medical user but they're engaged in non-medical use of
13 opioids; correct?

14 **A.** That could be the case.

15 **Q.** So it's Page 46. And it states in the first paragraph
16 under the heading I -- second paragraph there's a reference
17 to the fact that you reviewed 16 studies that found that
18 individuals who use prescription opioids non-medically.

19 All of the studies that you were looking at were
20 non-medical?

21 **A.** No, that's not correct. There were many individuals in
22 those 16 studies who used opioids medically.

23 **Q.** But all of the studies were looking at non-medical use
24 of opioids?

25 **A.** Not necessarily. The studies varied in terms of the,

1 the populations that were examined. And, so, there are many
2 examples in these studies of individuals who used medically.

3 **Q.** That's not the question I'm asking, Dr. Keyes. The
4 question I'm asking is that all of the 16 studies that you
5 relied on for your analysis of gateway were based on people
6 who were using opioids non-medically. Whether they were
7 also people who held a prescription or not, they were all
8 non-medical users. They were all studying non-medical
9 users.

10 **A.** That's not the case. I think if you go and look at the
11 studies, there are several in which there's information
12 about medical users.

13 **Q.** So where it states, "I reviewed 16 studies that found
14 individuals who used prescription opioids non-medically."
15 16 studies looked at individuals who used opioids
16 non-medically. That was the study set you looked at;
17 correct?

18 **A.** If you look at the populations that comprised the
19 studies, there were individuals who were using opioids
20 non-medically, many people for whom, you know, their first
21 prescription was based on back pain, et cetera. Some of
22 them went on to use non-medically. Some of them went on to
23 use heroin.

24 Maybe that sentence is inartfully worded, but they were
25 certainly using opioids non-medically in that they use

1 heroin. But not all of them were non-medical prescription
2 opioid users.

3 **Q.** Dr. Keyes, your testimony is that you relied on studies
4 that did not involve non-medical use of opioids?

5 **A.** Well, they were all heroin users. So in that sense --

6 MR. FARRELL: Objection, Your Honor, asked and
7 answered. And if he wants to ask about a particular
8 provision in the report, I would ask that he simply show it
9 to the witness.

10 THE COURT: Yeah. I'll sustain the objection. We
11 need to get through this, Mr. Hester.

12 BY MR. HESTER:

13 **Q.** If you look back at the Muhuri paper that I showed
14 you earlier, Exhibit 2647, that's one involving
15 non-medical pain reliever use; correct?

16 **A.** Again, the, the patient populations or those groups
17 overlap, so it's not only non-medical use, although they
18 measured non-medical use.

19 **Q.** You're not aware of any studies that have found that
20 people who use prescription opioids only medically have
21 higher rates of heroin use; correct?

22 **A.** I do. I am aware of one. It was published after this
23 report.

24 **Q.** Which one are you referring to?

25 **A.** McCabe 2020.

1 Q. Let me ask you to look, please, at your deposition
2 testimony out of New York.

3 A. What was the date of the deposition?

4 Q. Page -- and McCabe is not disclosed in your report?

5 A. It was published after the report and after the
6 deposition. But I have knowledge of it and you asked me if
7 I know of any study.

8 Q. At the time you wrote your report, there were none that
9 had found that people who use prescription opioids only
10 medically have higher rates of heroin use; correct?

11 A. At the time the report was published, there had not
12 been a study of that. And now there has been.

13 Q. So the studies that you were looking at involve a
14 transition from prescription opioids to heroin starting with
15 non-medical use?

16 A. I'm sorry. Say that again.

17 Q. The studies you were relying on involved a transition
18 from prescription opioids to heroin that started with a
19 misuse of prescription opioids?

20 A. That's not necessarily the case. As I said before,
21 there's a lot of -- a lot of these studies involve people
22 who started using opioids medically.

23 Q. And then transitioned to non-medical use; correct?

24 A. They transitioned to heroin use which is a non-medical
25 use of an opioid.

1 **Q.** Let me ask you in relation to your gateway theory, you
2 understand that criminals are responsible for manufacturing
3 illegal opioids like heroin; correct?

4 **A.** I have to correct you. It's not a gateway theory.
5 It's not a theory. There's data. So it's a gateway effect.

6 **Q.** But you've testified to -- I will ask you more
7 questions about that.

8 **A.** Okay.

9 **Q.** So in relation to your view that there's a transition
10 from prescription opioids to heroin, I wanted to ask you
11 about the heroin side of that equation. That involves
12 criminal conduct by drug dealers; correct?

13 **A.** Yes.

14 **Q.** And, so, criminals are responsible for trafficking the
15 illegal drugs that somebody transitions to; correct?

16 **A.** As far as I know.

17 **Q.** And then in order for the heroin to cause any harm, the
18 end-user actually needs to use it; correct? Needs to use
19 the heroin in order for there to be harm?

20 **A.** Yes.

21 **Q.** So, so for someone to use an illegal opioid like
22 heroin, there would be at least three crimes committed;
23 right?

24 **A.** I, I'm not a legal scholar, so I don't know all the
25 crimes that are committed when someone uses heroin.

1 **Q.** But a transition to, to heroin from a prescription
2 opioid would involve criminal conduct in relation to heroin;
3 correct?

4 MR. FARRELL: Objection, Your Honor, outside the
5 scope of her expertise, calls for a legal conclusion,
6 validation.

7 THE COURT: Overruled. I think this is proper
8 cross.

9 THE WITNESS: Can you restate the question?
10 BY MR. HESTER:

11 **Q.** The -- for someone to transition from prescription
12 opioids to heroin, there would have to be illegal acts
13 involving the, the manufacture, sale, and use of the
14 heroin; correct?

15 **A.** I would imagine, yes.

16 **Q.** I've written on the board, Dr. Keyes, "depends on
17 criminal conduct."

18 So let's talk a little bit more, Dr. Keyes, about your
19 definition of causation.

20 First, I want to make sure we're all on the same page
21 about terminology.

22 When you use the term "cause," you're using that term
23 as it's used by epidemiologists; correct?

24 **A.** That's right.

25 **Q.** An epidemiologists considers something a cause if it's

1 a factor that contributes, at least in part, to the
2 development of an illness, at least in some individuals;
3 correct?

4 **A.** Yes, something without which the outcome would not have
5 occurred when and how it did is the common definition we use
6 in our classes.

7 **Q.** So under the epidemiologist definition of cause that
8 you're applying, the cause need not be temporally proximate
9 to the outcome; correct?

10 **A.** That's right.

11 **Q.** And it's true that a cause can occur early in life and
12 an intervening cause can occur later in life and those could
13 still be causes for an epidemiologist; correct?

14 **A.** Yes.

15 **Q.** And there can also be multiple causes for a single
16 event; correct?

17 **A.** Yes.

18 **Q.** Causes, as you use the term, can be distant in time;
19 correct?

20 **A.** Can be?

21 **Q.** Distant in time?

22 **A.** Yes.

23 **Q.** And causes can come before or after one another in a
24 sequence of causes; correct?

25 **A.** Yes.

1 **Q.** So a cause does not need to be the closest or the most
2 recent cause to be considered a cause by an epidemiologist;
3 correct?

4 **A.** That's right.

5 **Q.** A cause does not need to be the primary or most
6 important cause to be considered a cause by an
7 epidemiologist; correct?

8 **A.** I don't know what you mean by primary or most
9 important.

10 **Q.** In other words, there could be multiple causes that
11 might have different weights and they might all be viewed as
12 causes by an epidemiologist; correct?

13 **A.** I don't know what you mean by different weights.

14 **Q.** Something does not need to be the direct cause to be
15 considered a cause by an epidemiologist, does it?

16 **A.** Again, this is not terminology that I'm familiar with.
17 And, so, I'm not sure what's the direct cause.

18 **Q.** So, so you don't evaluate the question of direct causes
19 in your work as an epidemiologist?

20 **A.** I guess if you could provide the definition of
21 "direct." I mean, we have a definition of "cause" and
22 "causation" that we use when we evaluate the literature.

23 **Q.** Let me see if I can get at it another way.

24 I take it, first, you do recognize that there's an
25 important difference between association and causation;

1 correct?

2 **A.** Causation is a subset of association. They're not
3 different.

4 **Q.** So there could be two events or two things that are --
5 have an association with each other that -- where there's
6 not causation; correct?

7 **A.** Yes.

8 **Q.** And you could also have some event that happens
9 temporally prior to another event, and the first event is
10 not necessarily the cause of the second; correct?

11 **A.** Yes.

12 **Q.** So an association means that there's a relationship
13 between two or more variables; correct?

14 **A.** Yes, one -- the outcome occurs with greater frequency
15 in the exposed and the unexposed, for example.

16 **Q.** And that doesn't necessarily mean that one variable in
17 the association causes the other?

18 **A.** It doesn't necessarily mean that.

19 **Q.** And, so, in assessing whether an association is causal,
20 you have to account also for other potential causes;
21 correct?

22 **A.** That would be a consideration of alternative
23 perspectives in the criteria that I've evaluated.

24 **Q.** You're familiar with the concept of multifactorial
25 diseases; correct?

1 **A.** I am.

2 **Q.** And that's when a single cause does not produce the
3 disease but, rather, the disease is the result of a
4 combination of many causes?

5 **A.** More than one.

6 **Q.** And is it the case that most diseases are
7 multifactorial?

8 **A.** I'm not sure if I would say most, but many diseases are
9 multifactorial.

10 **Q.** And OUD is a multifactorial disease; correct?

11 **A.** Well, there's one necessary cause, and then there are
12 other potential causes as well.

13 **Q.** So when you refer to OUD as, as a multifactorial
14 disease, that means that there's no single cause; there's,
15 there's multiple causes?

16 **A.** There's one necessary cause, and then there are other
17 contributing causes.

18 **Q.** And when you say one necessary cause, you're meaning
19 there has to be some exposure at some time to an opioid or
20 else you would never develop an OUD?

21 **A.** That's right.

22 **Q.** But, otherwise, there could be other multiple causes
23 that also contribute to the development of OUD in an
24 individual?

25 **A.** Yes.

1 **Q.** And it's also true, isn't it, that if you don't know
2 about the other causes of a disease, you may make incorrect
3 causal inferences based on measures of association from
4 epidemiological studies?

5 **A.** No, I wouldn't say that that is true across the board.
6 It really depends on the research question that you're
7 looking at. We in epidemiology call it black box
8 epidemiology, for example.

9 If you do an experiment, you might not know every
10 single contributing cause of the outcome. But as long as
11 the exposure is randomly assigned or that you can control
12 for enough factors that, you know, net of those controls,
13 you can make inference. You don't need to know every single
14 contributing cause. That's the whole kind of basis for
15 epidemiology that we can infer causation from group
16 comparison.

17 **Q.** But there are circumstances where if you haven't fully
18 identified other causes, you can make incorrect causal
19 inferences; correct?

20 **A.** It would really depend on the specific situation. I
21 can't answer that in the abstract.

22 **Q.** Now, Dr. Keyes, there was a heroin problem in the
23 United States well before there was an opioid crisis;
24 correct?

25 **A.** There has been heroin prevalent in the United States at

1 various levels at various times for as long as we've been
2 measuring drugs.

3 **Q.** And, and you recall previously we've discussed your
4 allocation of overdose deaths to prescription opioids the
5 way you had done your indirect and direct allocations;
6 right?

7 **A.** Yes.

8 **Q.** And you attributed 53.4 percent of the illicit opioid
9 deaths indirectly to prescription opioids in your
10 methodology; correct?

11 **A.** I don't think it was illicit opioids deaths. It was
12 all overdose deaths.

13 **Q.** The -- am I right that you -- your development of
14 deaths that you attributed indirectly due to prescription
15 opioids was based on a figure of 53.4 percent of those
16 deaths being attributed to prescription opioids?

17 **A.** Yes, opioid overdose deaths that were not directly
18 attributable to prescriptions.

19 **Q.** So for that group, the opioid overdose deaths that were
20 not directly attributed to prescription opioids in your
21 methodology, you used a 53.4 percent figure for that
22 attribution?

23 **A.** I did.

24 **Q.** And you took that attribution figure, that
25 53.4 percent, from NSDUH data on the number of heroin users

1 who reported having used prescription drugs before or at the
2 same time as their first use of heroin; is that correct?

3 **A.** That's right.

4 **Q.** And you believe that figure was reliable for the use in
5 allocating illegal opioid deaths as a result of your
6 analysis?

7 **A.** I do.

8 **Q.** Let me ask you to look at another document, please.

9 MR. HESTER: May I approach, Your Honor?

10 THE COURT: Yes.

11 BY MR. HESTER:

12 **Q.** Dr. Keyes, we've handed you a document marked as
13 Defendant's West Virginia Exhibit 2579. It's an article
14 written by Theodore Cicero and others, "Increased Use of
15 Heroin as an Initiating Opioid of Abuse: Further
16 Considerations and Policy Implications."

17 Do you see this document?

18 **A.** I do.

19 **Q.** And you've seen this document before I take it?

20 **A.** I have seen it before.

21 **Q.** And who --

22 **A.** I don't know that this is on my reference list, but I'm
23 familiar with the paper.

24 **Q.** Yes. I think, I think this is not listed on your
25 reference materials, but you do rely on other materials by

1 Theodore Cicero in your report; correct?

2 **A.** Yes. I, I know the paper. I don't think it's on my
3 reference list or on my materials considered list. I just
4 want to make that clear.

5 **Q.** What I wanted to ask you about is this statement
6 from -- in this Cicero paper, Page 2. And it's in the
7 right-hand column under the heading "Heroin as an Initiating
8 Opioid."

9 There's a statement that says, "Heroin use as a first
10 opioid grew sharply from 8.7 percent of the sample in 2005
11 to almost 31.6 percent in 2015."

12 Do you see that?

13 **A.** I do.

14 **Q.** And does that accord with your understanding that
15 heroin use as a first opioid has grown sharply over time and
16 is now roughly around 30 percent?

17 **A.** Well, this is a different population than the one that
18 I used for my calculation. So this is a population of
19 people who were, who were -- I'm not so familiar with the
20 methods as I didn't rely on it. But this is part of the
21 SKIP program, the Survey of Key Informant Patients. I don't
22 know what the sample size is. 5,885 people who -- I don't
23 know where they -- adults entering their substance abuse
24 treatment program with a primary diagnosis of opioid use
25 disorder.

1 Q. And so, so just to be clear on this, so this Cicero
2 study is looking at a population of people who are entering
3 treatment for opioid use disorder?

4 A. That's what it, it seems to be.

5 Q. And you're familiar with this paper?

6 A. I'm generally familiar with the paper.

7 Q. And, and my question was fairly narrow focusing on this
8 one sentence. Are you aware that there's been an increase
9 in heroin as a first opioid being used by people who are
10 reporting opioid use disorder?

11 A. This study shows that there has been an increase in
12 heroin use as the first opioid.

13 Q. And you're not aware of any contrary data in West
14 Virginia, are you?

15 A. Well, I guess I am in that if you look at the, at the
16 NSDUH data, for example, and other data sources they would
17 show different percentages. I haven't tried to adjudicate
18 between other sources at this point since I didn't rely on
19 the study.

20 Q. Well, this, this study reflects heroin use as the first
21 opioid rising to over 30 percent by 2015; correct?

22 A. This study has heroin use as the first opioid -- yes,
23 to 31.6 percent in 2015.

24 Q. And it's reflecting that that has been increasing;
25 correct?

1 **A.** In this sample, that percentage increased.

2 **Q.** And does that accord with your general understanding
3 that there has been, there has been an increase in opioid --
4 in heroin with the opioid first initiation?

5 **A.** I have not undertaken that analysis.

6 **Q.** The Cicero paper reflects this analysis here; correct?

7 **A.** Well, the Cicero paper still shows that over 60 percent
8 of people started with prescription opioids, which is what's
9 in my report. So the 2015 data in Cicero is consistent with
10 my report that 60 percent started with prescription opioids.

11 **Q.** Well, but your report talks about 80 percent starting
12 with prescription opioids.

13 **A.** The NSDUH number is slightly smaller. So it's within
14 the range of the prevalences that I report. This is, this
15 is very consistent with what other studies have shown.

16 **Q.** But the Cicero data does reflect an increase in the
17 percentage of people using heroin as the first opioid;
18 correct?

19 **A.** In a -- in the small treatment-seeking sample which
20 does not generalize noise. There are other literature to
21 corroborate it. This sample showed an increase, although
22 prescription opioids remain much more prevalent.

23 **Q.** And if you take the Cicero number, it's, it's lower
24 than the 80 percent number that you cited in your report as
25 reflecting prescription opioids as the opioid of first use;

1 correct?

2 **A.** Well, it is within the range of what I report in the
3 report on the proportion of people who began using
4 prescription opioids before heroin.

5 **Q.** And just to be clear, the NSDUH data, you reflect
6 nearly half of people reporting that prescription opioids
7 were the opioid of first use; correct?

8 **A.** Yes.

9 **Q.** Not 80 percent?

10 **A.** Yes. And I go into detail in the report on the
11 differences between that number and why I used it versus
12 other numbers that are closer to what Cicero reports of
13 60 percent starting with prescription opioids.

14 **Q.** You don't know whether the percentage of heroin users
15 who started with heroin as their first opioid has increased
16 since 2015, do you?

17 **A.** No.

18 **Q.** You published 306 peer-review articles I believe you
19 said, Dr. Keyes; is that right?

20 **A.** Yes.

21 **Q.** And between 35 and 40 of those articles relate
22 specifically to opioid use and related harms; correct?

23 **A.** That's right.

24 **Q.** And you've never published an article stating that
25 prescription opioid use causes later heroin use; correct?

1 **A.** I believe my scientific writings would be consistent
2 with the gateway effect. There's really no debate in the
3 literature on that.

4 So my articles that have been on prescription opioid
5 use and other related harms due to opioid use, including I
6 think the paper that we talked about earlier today in the
7 Annual Review of Public Health, certainly would reflect that
8 opinion.

9 **Q.** You've never, you've never published an article
10 saying -- stating that prescription opioid use causes later
11 heroin use?

12 **A.** I don't know that that sentence has ever appeared, but
13 it's certainly in the papers, all the, those opinions that
14 reflect the scientific consensus that is in the articles
15 that I've written on opioid use.

16 **Q.** No, but I'm really asking a very narrow question which
17 is have you stated the conclusion that prescription opioid
18 use causes later heroin use? And you have not; correct?

19 MR. ACKERMAN: Objection, asked and answered.

20 THE COURT: Overruled.

21 THE WITNESS: I don't believe that sentence -- I
22 don't know if that sentence has ever appeared in those 35 to
23 40 articles, but it's possible those combination of words
24 have not.

25 BY MR. HESTER:

1 **Q.** And there's, there's no other article that has
2 stated that conclusion, no public article published by
3 anyone else stating that prescription opioid use causes
4 later heroin use; correct?

5 **A.** I would have to disagree with that. I mean, I think
6 the information I've cited in this report consistently
7 shows, including from Nora Volkow and others, that
8 prescription opioids and heroin are pharmacologically
9 similar; that there's a high rate of transition between the
10 two, or higher than people who don't use prescription
11 opioids. And all of that information is consistent in those
12 scientific articles.

13 You know, scientists in general, and especially
14 epidemiologists, we talk about the data and the evidence.
15 That's what we do in our articles. So I think that that's
16 really clear in the literature.

17 **Q.** Dr. Keyes, the reports that you're referring to are
18 ones that state an association between prescription opioid
19 use and misuse and later heroin use; correct?

20 **A.** I would have to disagree.

21 **Q.** Those are the reports you're referring to?

22 **A.** I disagree. I think that the -- what's written in the
23 article, if you look at the Public Health Association report
24 of all the schools of public health, there is consistent
25 language and literature that would, would indicate that

1 there is a scientific consensus that this is a causal
2 relationship.

3 **Q.** And you state -- and you're asserting that that is
4 found in the 16 studies that you've relied on in your
5 report?

6 **A.** I'm sorry. That what is found?

7 **Q.** Do you, do you assert that the 16 studies you've relied
8 on in your report find causation, find that prescription
9 opioid misuse causes later heroin use?

10 **A.** That's not what my testimony was. My testimony is that
11 there is sufficient consensus across the materials that I
12 relied on that this is a causal relationship.

13 I independently undertook my own analysis of those 16
14 studies and others and compared it to the frameworks that we
15 use in public health for making decisions about causation.

16 So I think what we talked about on Friday was that any
17 one study is not sufficient to go from association to
18 causation. But then when you look at the body of
19 literature, that's what, that's what epidemiologists do.
20 And that's what I and others have done that are cited in
21 this report.

22 **Q.** But let me stay very narrowly focused on the 16 studies
23 you relied on. And those 16 studies, none of those studies,
24 none of those studies goes beyond finding an association to
25 finding causation between prescription opioid use and later

1 heroin use?

2 MR. ACKERMAN: Objection, asked and answered and
3 misstates prior testimony.

4 THE COURT: I think it has been, Mr. Hester.

5 MR. HESTER: Let me ask to pull up the New York
6 *Frye* transcript, please, Page 166.

7 BY MR. HESTER:

8 **Q.** So this is the -- let me go back to the first page.
9 So this is the testimony you gave in the *Frye* hearing in
10 September, 2020. Is that right, Dr. Keyes?

11 **A.** Yes.

12 **Q.** Let me ask you to look at the question and answer at
13 Page 166, lines 3 to 7.

14 There's a question that was asked you, "Going back to
15 that distinction we drew between causation and association,
16 am I accurate that none of those studies make the step of
17 going beyond association to causation?" That was the
18 question.

19 And your answer was, "No one study alone, no."

20 Was that your answer?

21 **A.** That's what I just said.

22 MR. FARRELL: Objection, Your Honor.

23 THE COURT: Yes.

24 MR. FARRELL: This isn't impeachment. This is
25 validation of what she testified to.

1 THE COURT: Well, I know.

2 I've got the point, Mr. Hester. You're going to have
3 to move along.

4 MR. HESTER: All right, Your Honor, I'll move it
5 on.

6 BY MR. HESTER:

7 Q. On Friday, Dr. Keyes, you testified about a study
8 that Banerjee and colleagues had prepared relating to
9 Veterans Administration data; right?

10 A. Yes.

11 Q. And you testified that Banerjee is a protective --
12 sorry. You testified that Banerjee is a perspective study
13 that follows groups of prescription opioid users and
14 non-users to determine the risk of heroin initiation; right?

15 A. Yes. I assume there's a copy of the study that I can
16 look at.

17 Q. Yes. I can get that for you.

18 MR. HESTER: May I approach, Your Honor?

19 BY MR. HESTER:

20 Q. Dr. Keyes, we've handed you what's been marked as
21 Defendants' West Virginia Exhibit 2436, "Non-Medical Use
22 of Prescription Opioids is Associated with Heroin
23 Initiation Among U.S. Veterans."

24 Do you see that?

25 A. I do.

1 **Q.** And is this the Banerjee article that you were
2 discussing?

3 **A.** It is.

4 **Q.** And it's headed again -- it's focusing on non-medical
5 use of prescription opioids; correct?

6 **A.** Well, again, not exactly. I mean, it's asking about
7 non-medical -- the, the questions that they asked queried
8 non-medical use, but there is quite a bit of overlap,
9 especially in the veteran population, between medical and
10 non-medical use.

11 **Q.** And do you understand -- if you look at Page --

12 MR. FARRELL: Excuse me, Mr. Hester.

13 MR. HESTER: Yes.

14 MR. FARRELL: Is this the -- is this the same
15 article that we talked about yesterday?

16 MR. HESTER: Uh-huh.

17 BY MR. HESTER:

18 **Q.** Am I right, Dr. Keyes -- I understood this was the
19 Banerjee article you had discussed in your testimony on
20 Friday.

21 **A.** Look at the Results section because these authors do
22 publish a lot. Yes, I believe it is.

23 MR. FARRELL: I'm sorry. The format threw me off.

24 I'm sorry. My apologies.

25 BY MR. HESTER:

1 **Q.** And do you see at the top of Page 3 of this
2 article, Dr. Keyes, it refers to people who engage in
3 non-medical use of prescription opioids may be at higher
4 risk for transition to heroin use? Do you see that,
5 first line?

6 **A.** Yes. It says, "Persons who engage in non-medical use
7 of prescription opioids may be at higher risk for
8 transitioning to heroin use in part because heroin has
9 become more accessible and less expensive than prescription
10 opioids in many U.S. settings."

11 **Q.** Does that accord with your understanding?

12 **A.** Yes.

13 **Q.** And, so, this is talking about persons who are engaged
14 in non-medical use of prescription opioids; right?

15 **A.** Well, not non-medical only. So it leads to non-medical
16 use.

17 **Q.** But they have to be engaged in some non-medical use to
18 be part of this analysis; correct?

19 **A.** To be a part of the exposed group. There's also an
20 unexposed group who did not use prescription opioids.

21 **Q.** And, so, this -- the study population that they were
22 looking at, if you look at Page 2, was a group of HIV
23 infected and uninfected veterans; is that right?

24 **A.** Yes.

25 **Q.** And approximately 45 percent of the participants in

1 this study were HIV infected; right?

2 **A.** That's right.

3 **Q.** And the authors go on to -- if you look at Page 8, the
4 authors state -- if you look at the bottom paragraph -- that
5 the study enrolled individuals who are likely at higher risk
6 for heroin initiation than the general veteran population.

7 Do you see that?

8 **A.** Yes.

9 **Q.** And does that accord with your understanding?

10 **A.** Yes. That's why we use a broad range of studies to
11 draw conclusions from in the literature.

12 **Q.** And it also goes on at Page 9, the last sentence, next
13 to the last sentence of the article. It says -- states that
14 the demographics of a veteran population are substantially
15 different from young college students.

16 Do you see that?

17 **A.** Yes.

18 **Q.** And does that also accord with your understanding?

19 **A.** That college students are a different demographic than
20 middle-aged veterans?

21 **Q.** The veterans being studied in this report.

22 **A.** Yes.

23 **Q.** And then if you look at Page 4 of this document, the
24 study -- the survey that was being measured was looking at
25 persons who used prescription opioids non-medically either

1 prior to or concurrent with initiation of heroin use; is
2 that right?

3 **A.** I'm sorry. What sentence are you --

4 **Q.** If you look at -- if you look in the middle of the
5 page, the end of the paragraph under "Measures," they refer
6 to new onset, NMUPO, was considered to occur prior to or
7 concurrently with heroin initiation.

8 Do you see that?

9 **A.** Yes.

10 **Q.** And, so, do you understand that this study was looking
11 at persons who had either engaged in non-medical
12 prescription opioid use before or concurrently with use of
13 heroin?

14 **A.** Well, it just -- I think the word "concurrently"
15 they're using here is in the same year.

16 **Q.** Right. So there could be heroin use and non-medical
17 use of prescription opioids in the same year and those would
18 be defined as concurrent use under the study; right?

19 **A.** That's right.

20 **Q.** So the authors' findings are not limited to people
21 whose non-medical prescription opioid use preceded heroin
22 initiation; correct?

23 **A.** By and large, the vast majority of the people in the
24 study who are in the risk group, they're looking at -- if I
25 could explain survival analysis for a moment.

1 The way survival analysis works, which is on Figure 2,
2 which is that you're measuring time from exposure to
3 outcome.

4 So the people who had prescription opioid use and
5 heroin use in the same year, their time to outcome is going
6 to be very, very short. So in Figure 2 they're going to be
7 part of that first bar of the time series graph.

8 And you can look at the time series graph and see the
9 blue line and the red line. And the red line is incident
10 NMUPO prior to or concurrent to heroin initiation, and then
11 the amount of time that has passed to their heroin
12 initiation.

13 So by far, what this study shows is that the people who
14 are using in the same year are not contributing to that five
15 times risk number that is in Table 2, I think it is, that I
16 spoke about on Friday.

17 **Q.** But --

18 **A.** Because, because of the way time series works, you
19 measure that -- the, the hazard of initiation is measured as
20 a factor of time.

21 **Q.** But the sample that this study is looking at includes
22 people who would initiate both heroin and non-medical use;
23 correct?

24 **A.** They didn't exclude those people, but the five times
25 risk number is not going to incorporate. They're largely

1 uninformative. If you're trying to -- if you can kind of
2 consider whether -- you know, you want to know what the risk
3 of heroin initiation is after you use prescription opioids.
4 So people who used in the same year are not contributing a
5 lot to that person time.

6 **Q.** Let me ask you about another document you discussed in
7 your examination on Friday. You discussed a report that was
8 put out by the Association of Schools and Programs of Public
9 Health; correct?

10 **A.** Yes.

11 **Q.** And you described that report as a consensus statement
12 of the schools; is that right?

13 **A.** Yes.

14 **Q.** Let me ask you to look at that paper for a minute,
15 please.

16 MR. HESTER: May I approach, Your Honor?

17 THE COURT: Yes.

18 BY MR. HESTER:

19 **Q.** Dr. Keyes, we've handed you what's been marked as
20 Plaintiffs' Exhibit 43124. It's entitled "Bringing
21 Science to Bear on Opioids."

22 Do you see that?

23 **A.** Yes.

24 **Q.** And this is the report you were talking about in your
25 examination on Friday; is that right?

1 **A.** That's right.

2 **Q.** And this is not an epidemiological study; correct?

3 **A.** It's a review of the literature which I would consider
4 to be an epidemiological study.

5 **Q.** It's a report of a task force of this Association of
6 Schools and Programs of Public Health; correct?

7 **A.** Yes. But contained in it is reviews of the literature.

8 **Q.** But it's a task force report. It doesn't purport to be
9 a consensus statement of all the schools in this
10 association; correct?

11 **A.** I believe on Page 3 that's what it says.

12 **Q.** But this is a task force report that was then
13 circulated by the Association of Schools and Programs?

14 **A.** You know, the ASPPH Board of Directors has reviewed and
15 endorsed the report.

16 **Q.** But it was prepared by a task force, not by a group of
17 schools; correct?

18 MR. ACKERMAN: Your Honor, asked and answered,
19 objection.

20 THE COURT: Sustained.

21 BY MR. HESTER:

22 **Q.** The -- let me ask you to look at the authors of the
23 report, please. If you look at the task force
24 members --

25 **A.** What page is that?

1 Q. It is Page 39 using the small numbers in the bottom
2 right. Do you see these are the members of the task force?

3 A. Yes.

4 Q. And is it your understanding that these are the folks
5 who prepared the report?

6 A. Let's see. Not exactly. On Page 3 it says, "After
7 much deliberation and extensive review of the scientific
8 literature, consultation with other experts, and the
9 practical experience of task force members."

10 Q. So --

11 A. So I would say that these are some of the people that
12 were centrally involved in the development of this document
13 certainly, but that it's not exclusively this group.

14 Q. Right. Okay. So these -- the listing here on Page 39
15 that we're looking at would reflect people who were
16 centrally involved in the task force report?

17 A. That would be my assumption.

18 Q. And do you know that Judith Feinberg listed here is an
19 expert witness in this case?

20 A. I'm not familiar with all of the other experts in the
21 case.

22 Q. Do you know that she is an expert witness in this case?

23 A. I heard her name this week when I was -- but I haven't
24 read her report.

25 Q. Do you know that Andrew Kolodny is an expert witness in

1 this case, another person listed in this membership of the
2 task force?

3 **A.** No.

4 **Q.** You don't know if he's an expert in this case?

5 **A.** I didn't know that. I know he has a lot of expertise
6 in opioid policy.

7 **Q.** Do you know he's an expert witness in other opioid
8 litigation?

9 **A.** I, I, I've heard his name referenced. I mean, he's an
10 expert on opioid use. It seems reasonable that he would
11 be --

12 **Q.** I was really asking about whether he's testifying as an
13 expert in this litigation.

14 **A.** I've heard his name in other litigation.

15 **Q.** Do you know -- do you see Caleb Banta-Green who's also
16 listed as one of the members of this task force?

17 **A.** Do I know him?

18 **Q.** Do you see his name listed there?

19 **A.** Yes.

20 **Q.** And do you know that he's at the University of
21 Washington and is an employee of the State of Washington?

22 **A.** That's what it says.

23 **Q.** And do you know that Washington State is suing these
24 defendants?

25 **A.** My understanding was that many states are suing.

1 Q. But Washington State, do you know that?

2 A. I'm not aware of every lawsuit.

3 Q. Do you see Brendan Saloner is also listed here in this
4 task force membership?

5 A. I see that.

6 Q. And if you look, if you look a few pages back at Page
7 47, there's a disclosure of conflict of interest issues.
8 And the last bullet on the page is, "Dr. Brendan Saloner
9 reported that he has a nondisclosure agreement with Monument
10 Analytics, a litigation consulting research firm run by a
11 colleague (Caleb Alexander)."

12 Do you see that?

13 A. Page 47?

14 Q. Yes.

15 A. Yes, I see that.

16 Q. And do you see that description of Dr. Saloner?

17 A. I see that description of Dr. Saloner.

18 Q. And are you aware -- it reflects here that he's a
19 colleague of Caleb Alexander. Do you see that?

20 A. Yes.

21 Q. And are you aware that Dr. Alexander is an expert
22 witness in this case?

23 A. I am.

24 Q. Let's turn back to the Muhuri study if we could. And I
25 wanted to go back, wanted to go back to your statement about

1 the 80 percent number, the 80 percent number being people
2 engaged in non-medical use of prescription opioids prior to
3 heroin transition. Do you recall that?

4 **A.** I do.

5 **Q.** And Muhuri is one of the papers you cite for that
6 proposition; right?

7 **A.** It is one, yes.

8 **Q.** So let's look, if you could, at Page 11 of this
9 document, please. And Table 3 here reports that percentage
10 of people who started using heroin based on different
11 factors that they present; correct?

12 **A.** Yes.

13 **Q.** And the last six rows on Page 11 give us data on the
14 percentage of heroin users with and without prior
15 non-medical pain reliever use; correct?

16 **A.** That's right.

17 **Q.** And, so, if we look over at the right-hand side we can
18 see this number of 79.5 percent; correct?

19 **A.** Yes.

20 **Q.** And that's the number that you cite prior --
21 non-medical prescription use prior to heroin initiation; is
22 that right?

23 **A.** That's right.

24 **Q.** And do you see also it states, if you look a little bit
25 further down, that it also indicates that -- how many of

1 these same individuals have prior illicit drug use before
2 their use of non-medical prescription opioids; correct?

3 **A.** Yes.

4 **Q.** And it reflects that 79.5 percent of persons engaged in
5 non-medical prescription use had prior use of illicit drugs;
6 correct?

7 **A.** Yes.

8 **Q.** So that's the same percentage as the percentage that
9 goes on to heroin; correct?

10 **A.** That's right.

11 **Q.** And if you look --

12 **A.** Well, it's not the percentage that goes on to heroin.
13 It's the percentage of heroin users who use non-medically
14 first.

15 **Q.** So the percentage -- 79.5 is the percentage of people
16 who engaged in non-medical use and then subsequently were
17 using heroin based on the Muhuri study; correct?

18 **A.** It's the proportion of heroin users who started opioid
19 use with prescription opioids.

20 **Q.** And, and this study also reflects that that same
21 proportion, that same 79.5 percent, had also used other
22 illegal substances before their use of non-medical
23 prescription opioids; right?

24 **A.** That's right.

25 **Q.** And if you look over on the next page, it defines the

1 illicit drugs that are referred to there. And it says, if
2 you look at Footnote 2, illicit drugs include marijuana,
3 hashish, cocaine, including crack, hallucinogens, and
4 inhalants. Do you see that?

5 **A.** I do.

6 **Q.** So according to this Table 3, every single heroin user
7 that had prior non-medical pain relieving use also had prior
8 illicit drug use; correct?

9 **A.** That's right.

10 **Q.** So prescription opioids were not the only drug of abuse
11 for any of the individuals who used prescription opioids
12 non-medically and then subsequently used heroin; correct?

13 **A.** Well, we only know from this not what their drugs of
14 abuse are, but that they had prior use of marijuana and
15 other drugs.

16 **Q.** So they had other -- they had abused other drugs before
17 their non-medical use of prescription opioids; correct?

18 **A.** I don't know that we know that they were before the
19 non-medical use of prescription opioids, but they did have
20 prior other illegal drug use like marijuana.

21 **Q.** And according to Table 3, nearly all of the heroin
22 users who did not have prior non-medical pain reliever use
23 had prior illicit drug use; is that correct?

24 **A.** Yes. Among those who -- with no prior non-medical pain
25 reliever use, 19.4 percent of the 20.5 percent had also used

1 another illegal drug.

2 **Q.** So if we add those two together, in this study
3 98.9 percent of the heroin users previously used illegal
4 drugs like marijuana, hashish, cocaine, crack,
5 hallucinogens, and inhalants; is that right?

6 **A.** That's right.

7 **Q.** So I'm going to put another entry on the board here.
8 What I've written there is "other substance abuse" to
9 reflect this finding of Muhuri.

10 **A.** Well, substance abuse is a DSM category. What this
11 study reflects is that they had other substance use.

12 **Q.** Other substance use of illegal drugs?

13 **A.** Other substance use of an illegal drug.

14 **Q.** So if I change that to "other substance use of illegal
15 drugs" is that more accurate?

16 **A.** Yes.

17 **Q.** And as a more general proposition, it's true, Dr.
18 Keyes, that a majority of heroin users started using
19 marijuana or cocaine or other illegal drugs before they
20 turned to heroin; correct?

21 **A.** Among heroin users, the most common first substance use
22 is tobacco and alcohol. And there is then a progression to
23 other drugs as well. But the, the timing of those vis-à-vis
24 prescription opioid use is quite variable.

25 **Q.** But --

1 **A.** Most people who use heroin have used alcohol and
2 tobacco. And then there are other drugs that are used as
3 well. But the timing of those is, is variable across
4 studies.

5 **Q.** But it's fair to say that a majority of heroin users
6 started using marijuana or cocaine or other illegal drugs
7 before turning to heroin; correct?

8 **A.** Yes, that is correct. It's the timing vis-à-vis
9 prescription opioids that is, I think, more relevant.

10 **Q.** But you could have a circumstance where persons who
11 used heroin began by abusing another drug like cocaine or
12 marijuana and then used prescription opioids, then used --

13 **A.** In this circumstance, because of the pharmacological
14 similarity between prescription opioid use and heroin use,
15 it's a much tighter connection in terms of that transition
16 because oftentimes people who don't have access to
17 prescription opioids, that becomes a catalyst for that
18 transition as drugs become less accessible and more
19 expensive.

20 **Q.** I take it, though, that you could have -- and you have
21 observed this sequence of events where persons who use
22 heroin began their abuse of illegal drugs with something
23 like cocaine or marijuana or methamphetamine. Then they may
24 have used prescription opioids, misused prescription
25 opioids, then later used heroin. Correct? That's a

1 sequence you've seen?

2 **A.** I only reviewed the aggregate data. And by far, the
3 biggest risk factor is prescription opioid use. Certainly,
4 I'm sure there is a person in the world who used cocaine
5 before heroin.

6 **Q.** Well, I was really asking another question which was
7 you're aware that many of the persons who used heroin after
8 misusing prescription opioids also had previously abused
9 other drugs?

10 **A.** I think what these data show is that there's previous
11 use of other drugs.

12 **Q.** And when you say other drugs, you're meaning marijuana,
13 cocaine, methamphetamine, et cetera; correct?

14 **A.** There is co-occurring use of other drugs. And alcohol
15 and tobacco, I think, would be appropriate to add to that
16 list as well. But the closest connection in the transition
17 to heroin is the exposure to prescription opioids.

18 **Q.** It's also true -- I think you said this before -- that
19 a majority of heroin users have used alcohol before they
20 started using heroin?

21 **A.** Used alcohol.

22 **Q.** How about abused?

23 **A.** I haven't done a recent search of the literature for
24 that. But certainly in terms of alcohol use, the vast
25 majority of people who have used heroin have used alcohol.

1 MR. HESTER: Let me pull up the New York *Frye*
2 transcript, please, Page 188, lines 3 to 10.

3 BY MR. HESTER:

4 Q. Dr. Keyes, I take it you recall testifying in this
5 *Frye* hearing in New York?

6 A. Yes.

7 Q. And the question was, "Do you know what percentage of
8 people who have used heroin abused alcohol before using
9 heroin?"

10 And you said, "Abused alcohol? Do you mean have
11 alcohol use disorder?"

12 And the question was, "Or abused it in some way, used
13 it excessively in some way."

14 And your answer was, "It's a majority."

15 Do you see that?

16 A. Yes.

17 Q. And was your answer correct when you gave it?

18 A. And that's what I just said. They used alcohol, not
19 alcohol use disorder, which is the distinction I was trying
20 to make. So that's consistent.

21 Q. But the question was abused it in some way or used it
22 excessively. And that's --

23 A. Used excessively is very different than having an
24 alcohol use disorder.

25 Q. Your own research has shown that past-year drug use,

1 other than non-medical use of prescription opioids and
2 alcohol use disorder, are the strongest factors associated
3 with non-medical use --

4 **A.** I'm sorry. Can you say the question again?

5 **Q.** Yes, sorry. Your own research has shown that past-year
6 drug use, other than non-medical use of prescription opioids
7 and alcohol use disorder, are the strongest factors
8 associated with non-medical use of prescription opioids.

9 Correct?

10 **A.** You said past -- I'm sorry. I don't think the question
11 quite -- unless I'm misunderstanding and it's the end of the
12 day, but I think you just said using drugs other than
13 prescription opioids is the strongest risk factor for using
14 prescription opioids other than -- it's a little bit
15 tautological the way that it's phrased.

16 **Q.** Fair enough. Let me see if I can ask it again.

17 Is it correct, Dr. Keyes, that past-year drug use is
18 the strongest factor associated with non-medical use of
19 prescription opioids?

20 **A.** Strongest compared to what?

21 **Q.** Strongest risk factor for incidence of non-medical use
22 of prescription opioids.

23 **A.** Exposure to opioids is the strongest risk factor.
24 There's a study that is potentially being taken out of
25 context. I'm sure we can look at it.

1 MR. HESTER: Let me pull up the New York *Frye*
2 hearing, please, 188, lines 3 to 8.

3 BY MR. HESTER:

4 Q. The question was asked, Dr. Keyes, "Am I right that
5 your own research has shown that past-year drug use --"

6 A. That's not what's shown on here.

7 Q. Sorry.

8 MR. HESTER: 188, lines 3 to 8, please. No.
9 Sorry. Lines 13 to 18. Apologies.

10 BY MR. HESTER:

11 Q. Okay. Am I right that -- the question was,
12 Dr. Keyes, "Am I right that your own research has shown
13 that past-year drug use, other than non-medical use of
14 prescription opioids and alcohol use disorder, are the
15 strongest factors associated with non-medical use of
16 prescription opioids?"

17 And your answer was, "Yes."

18 Correct?

19 A. Yes.

20 Q. And was that answer accurate when you gave it?

21 A. Yes, in the context of the other questions that had
22 positioned what those other factors we were comparing that
23 to was. We can't compare it to the universe of all risk
24 factors.

25 Q. That's a generally accepted view in the epidemiological

1 community as you expressed here on the screen; correct?

2 **A.** Again, you have to start with a list of the risk -- if
3 you're going to say this is the strongest risk factor, you
4 have to start with the list of risk factors you're
5 assessing.

6 The strongest risk factor for non-medical prescription
7 opioid use is exposure to opioids. If you're talking about
8 a different list of risk factors, drug use is certainly
9 correlated with non-medical use of prescription opioids, of
10 course. But you have -- to say what the strongest is, you
11 need some ranking.

12 MR. HESTER: Your Honor, I'm ready to go to
13 another document but --

14 THE COURT: Well, let's quit until in the morning,
15 Mr. Hester. I hope you can wrap this up pretty soon.

16 MR. HESTER: I will, Your Honor.

17 THE COURT: I've given you the whole day today and
18 we need to get this case moving.

19 MR. HESTER: Yes, Your Honor. And maybe if I
20 can -- I understand, first of all, what the Court is saying.
21 I will undertake to do that. If I can just give a bit of
22 perspective that we feel this is a very important piece
23 of --

24 THE COURT: Well, I understand that.

25 MR. HESTER: -- testimony and we felt we needed to

1 explain some of the methodologies. But I, I don't mean to
2 burn the Court's time and I'm not trying to. We'll be as
3 efficient as we can be.

4 THE COURT: Okay. Mr. Majestro has appeared in
5 the courtroom and --

6 MR. MAJESTRO: Your Honor, I just wanted to
7 inquire of the defendants. I don't want to beat a dead
8 horse, but we inquired Friday and we were told a little bit
9 after lunch to finish this cross-examination, verified that
10 over the weekend.

11 We've got a witness in from California who we thought
12 we were going to put in tomorrow. We've had a witness who
13 we were ready to put on this afternoon. We're starting to
14 stack them up.

15 I mean, it basically -- we agree this is an important
16 witness, but basically three-to-one cross-examination and
17 direct appears to us to be a bit on the excessive side.

18 THE COURT: Well, I'm getting very concerned about
19 us not getting things done here. And I realize this is an
20 extremely important witness and these are important points,
21 but at some point we've got to get this story told.

22 MR. MAJESTRO: Your Honor, may I inquire of
23 Mr. Hester how much time he has -- thinks he has left and
24 whether any of the other defendants are going to be
25 cross-examining so we can plan our witnesses?

1 MR. HESTER: Well, Your Honor, first of all, I'm
2 not sure that there was a representation made on Friday that
3 we were going to finish in X amount of time.

4 THE COURT: Well, are there -- will there be other
5 cross-examinations of this witness?

6 MS. MCCLURE: I am not cross-examining this
7 witness, Your Honor.

8 THE COURT: How about you, Ms. Hardin?

9 MS. HARDIN: There is a possibility that I would
10 have about a handful of questions, but I would like to have
11 the opportunity to consult with Mr. Hester before making any
12 final determinations about that.

13 THE COURT: Okay. Well, let's -- I understand
14 everybody's concerns and I don't have a ready answer for any
15 of this at 5:00 on Monday afternoon. So we'll reconvene at
16 9:00 in the morning and see where we are then.

17 MR. HESTER: And, Your Honor, I will undertake
18 overnight to look hard and make sure I'm tight in the
19 morning.

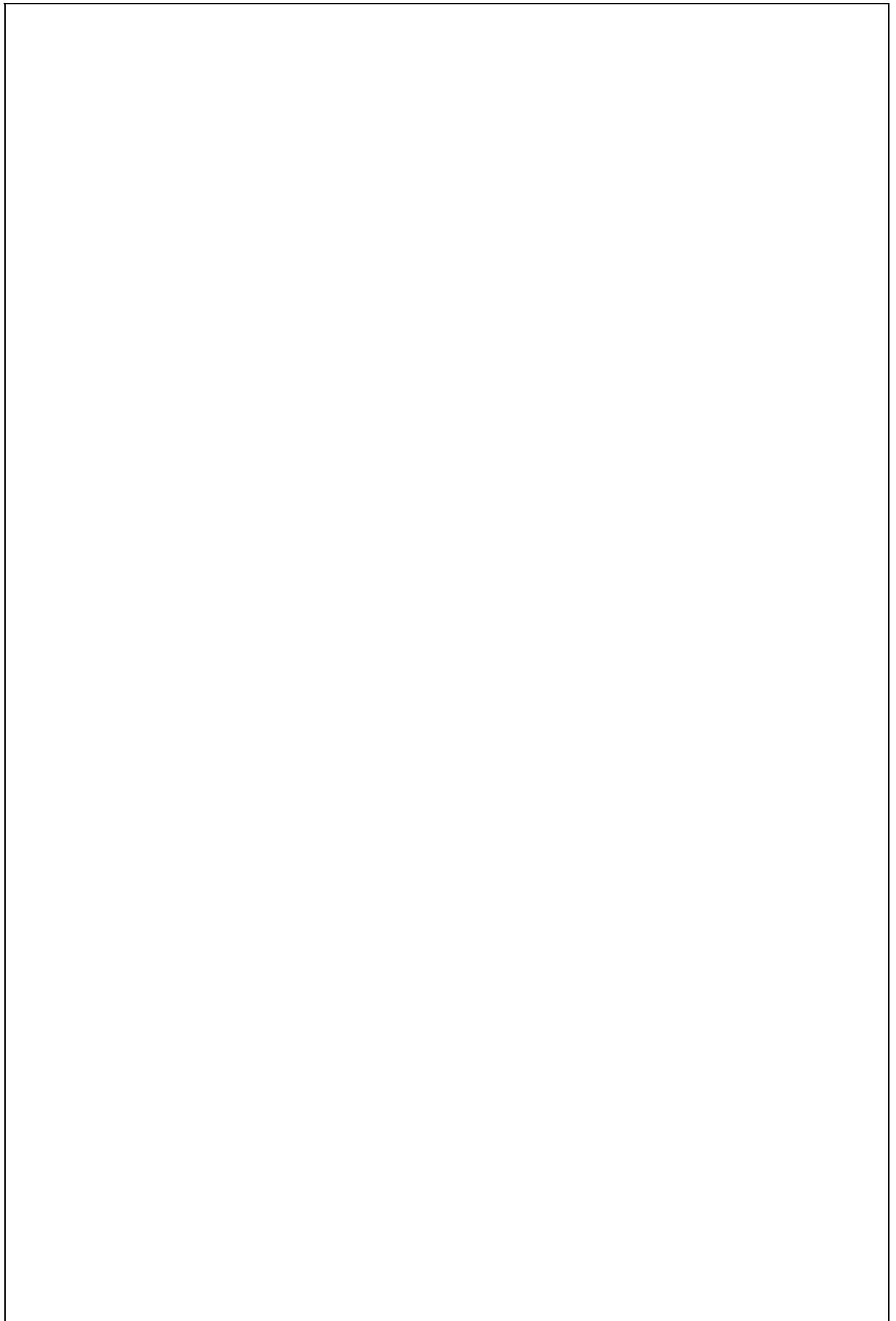
20 THE COURT: Thank you.

21 MR. MAJESTRO: If you could get us some estimate
22 as soon as you feel you're in a position to do so, that
23 would be helpful for planning purposes. We appreciate it.

24 THE COURT: Okay. We'll see everybody at 9:00.

25 (Trial recessed at 5:04 p.m.)

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1 CERTIFICATION:

2 I, Ayme A. Cochran, Official Court
3 Reporter, and I, Lisa A. Cook, Official Court Reporter,
4 certify that the foregoing is a correct transcript from
5 the record of proceedings in the matter of The City of
6 Huntington, et al., Plaintiffs vs. AmerisourceBergen
7 Drug Corporation, et al., Defendants, Civil Action No.
8 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as
9 reported on June 14, 2021.

10
11 S\Ayme A. Cochran

12 Reporter

13 s\Lisa A. Cook

14 Reporter

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16 June 14, 202117 Date
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